APPENDIX A

UNITED STATES COURT OF APPEALS
FEDERAL CIRCUIT

No. 02-1449

ALLERGAN, INC. AND ALLERGAN SALES, INC.,
Plaintiffs-Appellants,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD.,
AND ALCON UNIVERSAL, LTD.,
Defendants-Appellees,

and

BAUSCH & LOMB, INCORPORATED,
Defendant-Appellee.

DECIDED: March 28, 2003.

Before CLEVENGER, SCHALL, and LINN, Circuit Judges.

Opinion concurring in the judgment filed by Circuit Judge SCHALL, in which Circuit Judge CLEVENGER joins.

Opinion concurring in the judgment filed by Circuit Judge LINN.

PER CURIAM.

This appeal presents the question of whether the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355 and 360cc and 35 U.S.C. §§ 156 and 271) (the

"Hatch-Waxman Act"), allows an action for induced infringement based upon the filing of an Abbreviated New Drug Application ("ANDA"), in the following circumstances: (i) The patent at issue claims a method of using a specified drug for a particular purpose, but that use has not been approved by the Food and Drug Administration ("FDA") based upon a New Drug Application ("NDA"), (ii) the ANDA applicant seeks approval for the production of a generic version of the drug for a use that is different from the method of use of the drug that is claimed in the patent; and (iii) the generic drug that is the subject of the ANDA is effective for the method of use that is claimed in the patent.

This question arises in the context of a suit by Allergan, Inc. and Allergan Sales, Inc. ("Allergan") against Alcon Laboratories, Inc., Alcon Research, Ltd., and Alcon Universal, Ltd. ("Alcon"), and Bausch & Lomb, Incorporated ("B & L") for infringement of United States Patent Nos. 6,194,415 (the "'415 Patent") and 6,248,741 (the "'741 Patent"). The '415 patent claims a method of protecting the optic nerve through the administration of the drug brimonidine, while the '741 patent claims a method of neural protection through the administration of brimonidine. Brimonidine itself is not patented, and the FDA has not approved brimonidine for the uses claimed in the '415 and '741 patents. However, brimonidine is effective for those uses.[1]

---

[1] The FDA does not prohibit doctors from prescribing a drug for an unapproved or off-label use, and it does not prohibit patients from using a drug for an unapproved or off-label use. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356, 65 USPQ2d 1481, 1485 (Fed. Cir.2003) (stating that "a physician may prescribe an approved drug for any use consistent with acceptable medical practices . . . ."). Additionally, several states require doctors to prescribe a generic version of a drug, if available, for all approved and unapproved uses for which the drug is prescribed. *See, e.g.*, N.Y. Educ. Law § 6810(6)(a) (2002).

Allergan initiated suit in the United States District Court for the Central District of California after Alcon and B & L submitted ANDAs to the FDA seeking approval for the production and sale of a generic version of brimonidine for the reduction of intraocular pressure, a use different from the uses for brimonidine claimed in the '415 and '741 patents. Allergan charged Alcon and B & L with induced infringement under the authority of 35 U.S.C. § 271(e)(2).[2] In due course, Alcon and B & L filed motions for summary judgment of non-infringement, arguing that a claim of induced infringement is not cognizable under section 271(e)(2) where, as here, the ANDA is for a use of the drug that is different from the use of the drug that is claimed in the asserted patent. The district court agreed. Accordingly, it granted Alcon's and B & L's motions, dismissed Alcon's and B & L's non-infringement and invalidity counterclaims without prejudice, and certified the case pursuant to Fed.R.Civ.P. 54(b). *Allergan, Inc. v. Alcon Labs., Inc.*, 200 F.Supp.2d 1219, 63 USPQ2d 1427 (C.D.Cal.2002); *Allergan, Inc. v. Alcon Labs., Inc.*, No. SA CV 02-40 DOC (ANx) (C.D. Cal. Jun 4, 2002).

Prior to January 16, 2003, the question presented in this case represented an issue of first impression. On that day, however, a panel of this court decided *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 65 USPQ2d 1481 (Fed.Cir. 2003). In *Warner-Lambert*, this court held that "it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor the use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA." *Warner-Lambert*, 316 F.3d at 1354-55, 65 USPQ2d at 1484. Based upon *Warner-Lambert*, we affirm the district court's decision that the action for induced infringement brought by Allergan is not cognizable under 35 U.S.C. § 271(e)(2).

---

[2] All references are to statutes set forth in the 2000 version of the United States Code.

BACKGROUND

I. The Hatch-Waxman Act

We recently stated that, in the Hatch-Waxman Act, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371, 61 USPQ2d 1414, 1415 (Fed.Cir.2002). To accomplish the goals of the Act, Congress amended provisions of the patent statute and the Food, Drug, and Cosmetic Act ("FDCA").

Prior to the passage of the Act, all drug manufacturers, brand name and generic, had to perform controlled studies to demonstrate that a new drug would be safe and effective for its intended use.[3] This requirement resulted in long delays between the time when a brand name drug manufacturer received a patent for a new drug and the drug reached the market. It also resulted in long delays between the time when the patent expired and generic drug manufacturers were able to market a generic version of the drug. The Hatch-Waxman Act sought to address this situation by providing brand name drug manufacturers with limited extensions of their patent terms in order to restore a portion of the market exclusivity lost through the lengthy process of drug development and FDA approval. At the same time, to counter this benefit to the brand name manufacturers, the Act provided generic drug manufacturers with a patent infringement exemption for experimentation in connection with an application for FDA approval of a generic drug. It also provided a shortened FDA approval process for generic drugs. H.R.Rep. No. 98-857, pt.

---

[3] The FDA previously allowed ANDAs for pioneer drugs approved prior to 1962. H.R.Rep. No. 98-857, pt. 1, at 16 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.

1, at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.

Before a drug manufacturer can market a new drug, it must obtain FDA approval. 21 U.S.C. § 355(a). The approval process requires the submission of a NDA, which is the result of extensive testing and which must include safety information, efficacy information, and composition data. 21 U.S.C. § 355(b). Pursuant to the Hatch-Waxman Act, the FDA, upon approval of a NDA, grants the applicant a five-year period of exclusive marketing for the approved drug, which can be extended by six months if the producer submits safety information relating to children. 21 U.S.C. §§ 355(c)(3)(D)(ii) and 355a(a)(1)(A)(i). This period of exclusivity was primarily designed by Congress to encourage the development and testing of unpatentable pharmaceuticals. H.R.Rep. No. 98-857, pt. 1, at 29 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48. The FDA approval process requires a NDA applicant to file with its NDA the following:

> the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1). The holder of an approved NDA must file the same information with respect to similar patents that are obtained after the NDA is approved. 21 U.S.C. § 355(c)(2). The FDA lists such patents in a book entitled "Ap-proved Drug Products with Therapeutic Equivalence Evaluations." The book is commonly referred to as the "Orange Book." *Andrx,* 276 F.3d at 1371, 61 USPQ2d at 1415.

To attain a balance between the interests of brand name pharmaceutical companies and generic drug manufacturers, Congress, as part of the Hatch-Waxman Act, legislated that a

generic drug manufacturer may, without liability for infringement, use a drug claimed in a patent or a method of using a drug claimed in a patent in order to prepare an application for FDA approval of a generic drug. 35 U.S.C. § 271(e)(1). At the same time, Congress extended the ANDA process to post-1962 pioneer drugs to couple with the NDA process. A generic drug manufacturer may file an ANDA to obtain approval for a generic drug. 21 U.S.C. § 355(j). The ANDA must be for the same drug that has been approved by the FDA, or it must be for a drug that is the bioequivalent of a drug that has been approved by the FDA. 21 U.S.C. § 355(j)(2).

The ANDA process imposes a certification requirement with respect to patents covering the drug that has been approved by the FDA. A generic drug manufacturer must certify in its ANDA the following with respect to each patent "which claims the [drug previously approved by the FDA] or which claims a use for [that] drug for which the applicant is seeking approval . . . and for which information is required to be filed" for listing in the Orange Book: (i) such patent information has not been filed; (ii) the approved drug's patent has expired; (iii) the date the approved drug's patent will expire; or (iv) the approved drug's patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug for which the ANDA is being submitted (a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii); *see Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1244, 54 USPQ2d 1711, 1712 (Fed.Cir.2000). If a method of using the approved drug is patented and is listed in the Orange Book, but the manufacturer is not seeking approval for the patented use, the manufacturer must state in the ANDA that the method of use patent does not claim the use for which the manufacturer is seeking approval. 21 U.S.C. § 355(j)(2)(A)(viii).

As suggested by the certification process, a generic drug manufacturer may file an ANDA before a patent expires and, in so doing, allege non-infringement and invalidity of the patent.[4] The Hatch-Waxman Act provides that, in that situation, the filing of the ANDA is an act of infringement. 35 U.S.C. § 271(e)(2)(A); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568-69, 42 USPQ2d 1257, 1263 (Fed.Cir. 1997). The exemption to infringement under section 271(e)(1) allows a generic drug manufacturer to take the steps needed to bring a generic drug to market without waiting until the patent expires. At the same time, by deeming the filing of an ANDA to be an act of infringement under section 271(e)(2), the Hatch-Waxman Act allows a brand name drug manufacturer to challenge the ANDA application and a generic drug manufacturer to challenge the validity and infringement of an asserted patent before the patent expires. *Id.*

A generic drug manufacturer who files an ANDA containing a Paragraph IV certification must notify the owner of the unexpired patent that is the subject of the certification. 21 U.S.C. § 355(j)(2)(B)(i) & (ii). The patent owner then has 45 days to file an action for infringement in district court. 21 U.S.C. § 355(j)(5)(B)(iii). If suit is filed, the court then determines whether the applicant will, if the application is approved, infringe the patent at issue. *Glaxo*, 110 F.3d at 1569, 42 USPQ2d at 1263. If the patent owner does not file suit within the required time period, the ANDA may be approved immediately, subject to applicable FDA regulations. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent owner files an infringement action, the ANDA may not be approved until the date the court determines invalidity or non-infringement,

---

[4] A generic drug manufacturer may also file an ANDA after the corresponding NDA holder's fourth year of FDA granted market exclusivity ends, if the ANDA contains a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii). 21 U.S.C. § 355(j)(5)(D)(ii).

the date the patent expires, or 30 months from the date the patent holder receives notice of the ANDA Paragraph IV certification (subject to judicial discretion), whichever occurs first. *Id.*

II. The '415 and '741 Patents

This case arises out of Alcon's and B & L's efforts to market a generic version of Allergan's medication, Alphagan. Alphagan is used in the treatment of open-angle glaucoma, a disease of the eye that results in the deterioration of vision. Open-angle glaucoma is caused by damage to the optical cells, but it is unknown exactly how this damage occurs. For years, the accepted belief of the medical profession was that the disease was caused by exceptionally high intraocular pressure ("IOP"), resulting from a failure of the eye fluid, called aqueous humor, to properly drain. The high pressure in the eye presumably bore down on the optic nerve, thereby damaging it. Drug manufacturers sought pharmaceutical components that reduced IOP in the eye in order to treat glaucoma.

On September 6, 1996, Allergan obtained approval of its NDA for the drug, brimonidine, the chemical compound in Alphagan, for reducing IOP. As a result, Allergan received a five-year period of market exclusivity for brimonidine plus a six-month extension for researching the health effects and safety of the drug in children. This exclusive term expired on March 6, 2002. Brimonidine is not protected by a patent and is therefore in the public domain.

More recently, scientists have discovered that open-angle glaucoma also occurs in patients with low IOP. They therefore conjecture that it may be a neurodegenerative disease of the optic nerve. Upon further investigation, Allergan's scientists discovered that brimonidine helps prevent neurodegeneration. This discovery led Allergan to file for the '415 and '741 patents, each of which is a method of use patent. The

'415 and '741 patents do not claim the use of brimonidine for reducing IOP. That use, like the drug itself, is unpatented and in the public domain.

The '415 and the '741 patents claim methods of using brimonidine for treating ocular neural injuries, such as open-angle glaucoma. The '415 patent claims "[a] method of protecting the optic nerve and retina of a mammal comprising administering to said mammal suffering from or at risk of suffering a noxious action on said nerve cells an effective amount of [brimonidine] to inhibit or prevent nerve cell injury or death . . . ." '415 patent, col. 17, ll. 35-39, col. 18, ll. 1-25. The first dependent claim defines the noxious action as "glaucomatous optic neuropathy." '415 patent, col. 18, ll. 26-27. The '741 patent claims "[a] method of providing neural protection to a mammal comprising administering to said mammal suffering from or at risk of suffering a noxious action on its nerve cells an effective amount of [brimonidine] to inhibit or prevent nerve cell injury or death . . . ." '741 patent, col. 17, ll. 27-39, col. 18, ll. 1-8. The first dependent claim defines the noxious action as being "a result of a crushed or compressed nerve." '741 patent, col. 18, ll. 10-11. Both the '415 patent and the '741 patent are continuations-in-part of application number 08/496,262, now United States Patent No. 5,856,329 (the " '329 patent"). The '415 and '741 patents carry terminal disclaimers to the '329 patent. The '329 patent was filed on June 28, 1995. Therefore, due to the terminal disclaimers, all three patents expire on June 28, 2015. After the '415 and '741 patents issued in 2001, Allergan submitted information relating to the patents to the FDA so that they could be listed in the Orange Book.

III. Alcon's and B & L's ANDAs and Allergan's Lawsuit

In October of 2001, Alcon filed an ANDA for brimonidine, and in November of 2001, B & L filed one as well. In their ANDAs, Alcon and B & L stated that they were seeking approval from the FDA to produce and sell a generic version

of brimonidine for use in lowering IOP in patients with open-angle glaucoma or ocular hypertension. Neither Alcon nor B & L sought FDA approval for the methods of using brimonidine claimed in the '415 and '741 patents. As part of their respective ANDAs, Alcon and B & L filed Paragraph IV certifications, based on Allergan's Orange Book listings, indicating that Allergan's '415 and '741 patents were not infringed and that, to the extent Allergan asserted that the patents covered IOP lowering, they were invalid. After Alcon and B & L gave Allergan notice of the filing of their ANDAs for brimonidine, Allergan instituted suit against both companies in the United States District Court for the Central District of California within the 45 day time period set forth in 21 U.S.C. § 355(j)(5)(B)(iii). Allergan brought its suit under 35 U.S.C. § 271(e)(2), alleging that if the FDA approved Alcon's and B & L's ANDAs, Alcon and B & L would induce doctors to infringe the '415 and '741 patents by prescribing brimonidine for neuroprotection and would induce patients to infringe by using brimonidine for neuroprotection. Allergan also alleged that, through the submission of their ANDAs, Alcon and B & L were liable for infringement because they violated 35 U.S.C. § 271(e)(2) directly.

As noted above, Alcon and B & L moved for summary judgment of non-infringement, arguing that a claim of induced infringement is not cognizable under section 271(e)(2) where, as here, the ANDA is for a use of the drug that is different from the use of the drug that is claimed in the asserted patent. In ruling on the motions, the district court noted that, as far as Alcon was concerned, Allergan had presented sufficient evidence to present a triable issue of fact with regard to induced infringement, or had at least presented sufficient evidence to proceed to discovery.[5] *Allergan,* 200

[5] Responding to the summary judgment motions, Allergan presented evidence in the form of research papers, patents, and articles suggesting that the neuroprotective functions of brimonidine are well known in the

F.Supp.2d at 1225, 63 USPQ2d at 1431. The district court did not make a similar finding with respect to B & L. The district court, nevertheless, granted Alcon's and B & L's motions. Addressing Allergan's claim of induced infringement, the court held that the filing of an ANDA does not provide a predicate for a method of use patent holder to sue an ANDA applicant for induced infringement. *Id.* at 1232, 63 USPQ2d at 1437. The court viewed section 271(e)(2) as being symmetrical with section 271(e)(1), which, as noted above, allows a generic drug manufacturer to use a patented drug in order to prepare an application for FDA approval without liability for infringement. The court therefore reasoned that the type of claims that accrue upon the filing of an ANDA are limited to those claims that a patent holder could have brought in the absence of section 271(e)(1). The court stated that, had section 271(e)(1) not been enacted, Allergan could have sued Alcon for infringement for using its patent in the development of a generic drug. "It could not, however, sue Alcon for inducing infringement because there was yet to be any third-party infringement and thus the question of inducing infringement would be entirely too speculative." *Id.* at 1231, 63 USPQ2d at 1436. Under these circumstances, the district court concluded, "allowing a patentee to bring a claim for inducing infringement under [s]ection 271(e)(2) runs afoul of the 'case or controversy' requirement of Article III [of the Constitution]." *Id.* at 1232, 63 USPQ2d at 1437. The district court rejected Allergan's direct cause of action claim on the ground that section 271(e)(2) does not expand the traditional grounds of patent infringement; it requires the

---

medical field and that doctors are currently prescribing brimonidine for neuroprotective purposes. In addition, Allergan submitted evidence of instances where Alcon allegedly advertised an ANDA approved drug for uses other than those uses approved by the FDA. Finally, Allergan presented evidence indicating that Alcon and B & L have included articles on their websites that discuss brimonidine's neuroprotective properties.

same inquiry as any other infringement suit. *Id.* at 1227, 63 USPQ2d at 1433.

Allergan now appeals the district court's grant of Alcon's and B & L's motions for summary judgment. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Standard of Review

We review a grant of summary judgment by a district court *de novo*. *Cortland Line Co. v. Orvis Co.*, 203 F.3d 1351, 1355-56, 53 USPQ2d 1734, 1736 (Fed.Cir.2000). Summary judgment is appropriate where the record shows "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. R. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). We review a district court's interpretation of statutory language, which is a question of law, without deference. *Waymark Corp. v. Porta Sys. Corp.*, 245 F.3d 1364, 1366, 58 USPQ2d 1456, 1458 (Fed.Cir.2001). In this case, the issue before us is a question of law: whether the district court erred in holding that the Hatch-Waxman Act does not support Allergan's claim of induced infringement against Alcon and B & L.

II. Contentions of the Parties

On appeal, Allergan argues that the district court erred in construing 35 U.S.C. § 271(e)(2) so as to bar suits for induced infringement. Allergan contends that Congress enacted section 271(e)(2) to complement the filing of an ANDA, not to counterbalance 35 U.S.C. § 271(e)(1). Allergan further argues that, pursuant to section 271(e)(2), it may bring a suit for induced infringement of the '451 and '741 patents, even though Alcon's and B & L's ANDAs do not seek approval for the methods of using brimonidine claimed in those patents. In the alternative, Allergan urges that section

271(e)(2) provides a direct cause of action that makes Alcon and B & L liable for direct infringement based upon the filing of their ANDAs.

Alcon responds that the district court properly granted summary judgment against Allergan. Alcon argues that Allergan's suit cannot succeed for two reasons. First, according to Alcon, section 271(e)(2) only provides jurisdiction for an action for infringement of a method of use patent when the patent at issue claims an FDA-approved use and the ANDA applicant is seeking approval for that use. Second, Alcon asserts that, under section 271(e)(2), the conventional requirements for infringement under 35 U.S.C. § 271(a), (b), and (c) apply and that, in this case, there is no direct infringement by a third party and no evidence that Alcon has or will actively promote its generic drug for an infringing use. B & L joins in Alcon's arguments. In addition, it contends that Allergan has not shown any triable issue of fact with respect to its claim of induced infringement against B & L.[6]

For the reasons that follow, we hold that *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 65 USPQ2d 1481 (Fed.Cir.2003), controls this case and that, under *Warner-Lambert*, Allergan may not sue Alcon and B & L under section 271(e)(2) for inducing infringement of the '415 and '741 patents. We therefore affirm the district court's grant of summary judgment in favor of Alcon and B & L.

---

[6] The Washington Legal Foundation ("WLF") submitted an *amicus curiae* brief. WLF argues that the district court erred in ruling that Allergan's induced infringement claim does not present a case or controversy as required by Article III. WLF also argues that the plain language of section 271(e)(2) supports Allergan's contention that section 271(e)(2) allows its claim of induced infringement.

III. Whether 35 U.S.C. § 271(e)(2) is a Jurisdictional Statute

The district court stated that "[s]ection 271(e)(2) . . . provides no new substantive law, but much like the Declaratory Judgment Act, 28 U.S.C. § 2201, merely provides a jurisdictional 'hook' for a patent case." *Allergan*, 200 F.Supp.2d at 1227, 63 USPQ2d at 1433. On appeal, Alcon and B & L argue that section 271(e)(2) did not provide the district court with jurisdiction over Allergan's action because Allergan did not assert infringement of a method of use patent that claims an FDA-approved use for which Alcon and B & L are seeking FDA approval. Under these circumstances, we think it appropriate to address at the outset whether section 271(e)(2) is a jurisdictional statute.

Section 271(e)(2) is not a jurisdictional statute in the strict sense of the word. As the Supreme Court pointed out in *Eli Lilly Co. v. Medtronic, Inc.*, section 271(e)(2) creates an "act of infringement" based upon the filing of an ANDA. 496 U.S. 661, 678, 110 S.Ct. 2683, 110 L.Ed.2d 605, 15 USPQ2d 1121, 1130 (1990). We explained in *Glaxo* that section 271(e)(2) "provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo*, 110 F.3d at 1569, 42 USPQ2d at 1263. Once Congress creates an act of infringement, jurisdiction in the district court is proper under 28 U.S.C. § 1338(a). Section 1338(a) states that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . . ." Section 271(e)(2) is an Act of Congress relating to patents. Therefore, section 1338(a) provides for jurisdiction in the district court for Allergan's suit.

In short, section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed. The critical

question, and the one to which we now turn, is whether Allergan's claim of induced infringement against Alcon and B & L is cognizable under section 271(e)(2).

IV. Whether Allergan's Claim of Induced Infringement May be Brought Under 35 U.S.C. § 271(e)(2)

A. *Claims of Induced Infringement Under Section 271(e)(2) Generally*

Preliminarily, we must determine whether, as a general matter, section 271(e)(2) may serve as an umbrella for a claim of induced infringement for a method of use patent. As noted above, the district court concluded that it could not. The district court reasoned that the type of claims that accrue upon the filing of an ANDA are limited to those claims that a patent holder could have brought in the absence of section 271(e)(1), such as an infringement claim against a generic drug manufacturer for using the patent in the development of a generic drug. The district court determined that a claim of induced infringement, based upon conduct of a third party that would occur upon approval of an ANDA, was not a claim that a patent holder could have brought before the enactment of section 271(e)(1). *Allergan*, 200 F.Supp.2d at 1231, 63 USPQ2d at 1436. The district court concluded that "[s]ection 271(e)(2) . . . does not provide a predicate for Allergan to sue for inducing infringement." *Id.* at 1230, 63 USPQ2d at 1435.

We do not share the district court's view of 35 U.S.C. § 271(e)(2). To begin with, the language of section 271(e)(2) does not limit the reach of the statute to direct infringement actions to the exclusion of actions for induced infringement. Additionally, in *Glaxo*, we did not limit the scope of section 271(e)(2) to direct infringement actions. Instead, we stated that a court must employ a traditional infringement analysis, focusing on all of the elements of infringement. *Glaxo*, 110 F.3d at 1567, 42 USPQ2d at 1262 ("The plain language of the statute does not alter a patentee's burden of proving infringe-

ment . . . ."). The only difference in the analysis of a traditional infringement claim and a claim of infringement under section 271(e)(2) is the timeframe under which the elements of infringement are considered. *Id.* at 1569, 42 USPQ2d at 1263 ("[T]he question of infringement must focus on what the ANDA applicant will likely market if its application is approved . . . ."). *Glaxo* does not preclude patentees from asserting claims for induced infringement under 35 U.S.C. § 271(e)(2). In fact, a patent holder asserting infringement of a patent that claims a FDA-approved method of use for which an ANDA seeks approval will, in many instances, have to prove induced infringement. Therefore, section 271(e)(2) may support an action for induced infringement.

Finally, we do not agree with the district court that the "case or controversy" requirement of Article III of the Constitution precludes a patentee from bringing a claim of induced infringement under section 271(e)(2). The district court was of the view that, in the case of a claim of induced infringement predicated on direct infringement by third party physicians, there is "not a sufficiently immediate threat that there will be a violation of the patent laws so as to warrant judicial determination." *Allergan*, 200 F.Supp.2d at 1232, 63 USPQ2d at 1437.

The case or controversy clause in Article III of the Constitution requires injury in fact, connection between the challenged conduct and the injury, and redressability of the injury by the requested remedy. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998) ("This triad of injury in fact, causation, and redressability comprises the core of Article III's case-or-controversy requirement . . . ."). A claim under 35 U.S.C. § 271(e)(2) is, by its very nature, speculative to a certain degree, as acknowledged in *Glaxo*. *See Glaxo*, 110 F.3d at 1569, 42 USPQ2d at 1263 ("The only difference in actions brought under § 271(e)(2) [from actions brought under

section 271(a)] is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred."). While a section 271(e)(2) induced infringement claim may be speculative, it is not sufficiently so to contravene the case or controversy requirement. In *Glaxo*, we stated that section "271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo*, 110 F.3d at 1569, 42 USPQ2d at 1263. Additionally, in the setting of a declaratory judgment action, we have held that Article III does not preclude an action by a potential defendant for a determination that its conduct does not induce infringement, prior to any acts of infringement having taken place. *See Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1485, 46 USPQ2d 1461, 1467 (Fed.Cir.1998) ("[W]e decline . . . to create a per se rule that an actual controversy predicated only on induced infringement may exist only if direct infringement has already occurred."). Thus, under *Fina*, a method of use patent holder could potentially bring an action against a generic drug manufacturer for induced infringement under 35 U.S.C. § 271(b) on the day the ANDA was approved before a single prescription of the generic drug was written by third party physicians. *Id.* A claim of induced infringement under section 271(e)(2), filed prior to the occurrence of direct infringement, does not violate the case or controversy requirement of Article III.

Summary judgment of non-infringement under section 271(e)(2), therefore, is inappropriate where the plaintiff can demonstrate the existence of a genuine issue of material fact with respect to the claim that the ANDA filer will induce infringement of its patent upon approval of the ANDA. *Warner-Lambert*, 316 F.3d at 1356, 65 USPQ2d at 1485. The district court found that Allergan presented a triable issue of

fact with respect to induced infringement by Alcon sufficient to allow the parties to proceed to discovery. *See supra* note 5; *Allergan*, 200 F.Supp.2d at 1225, 63 USPQ2d at 1431. Allergan presented evidence that third-party doctors and patients will likely infringe its two method of use patents and that Alcon and B & L may knowingly induce this infringement through their actions. *See Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553, 16 USPQ2d 1587, 1594 (Fed.Cir.1990) ("The plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements.") (emphasis in original).

We must now determine whether Congress has prohibited the particular action for induced infringement brought by Allergan.

B. *Allergan's Action for Induced Infringement*

The district court concluded that, in the case of a method of use patent, section 271(e)(2) only makes the filing of an ANDA an act of infringement when the patent at issue claims the use for which FDA approval is sought in the ANDA. *Allergan*, 200 F.Supp.2d at 1230, 63 USPQ2d at 1435. Allergan argues that the district court erred in its ruling. For their part, Alcon and B & L contend that the district court correctly held that only when the ANDA speaks to the use that is claimed in the patent at issue may the patent holder bring suit under section 271(e)(2).

This issue was decided in *Warner-Lambert*. *Warner-Lambert* held that, pursuant to section 271(e)(2), a method of use patent holder may not sue an ANDA applicant for induced infringement of its patent, if the ANDA applicant is not seeking FDA approval for the use claimed in the patent and if the use claimed in the patent is not FDA-approved. *Warner-Lambert*, 316 F.3d at 1354-55, 65 USPQ2d at 1484. *Warner-Lambert* reasoned that "because an ANDA may not

seek approval for an unapproved or off-label use of a drug under 21 U.S.C. § 355(j)(2)(A)(i), it necessarily follows that 35 U.S.C. 271(e)(2)(A) does not apply to a use patent claiming only such a use." *Id.* at 1356, 65 USPQ2d at 1485.

In the *Warner-Lambert* case, Warner-Lambert obtained FDA approval through a NDA to market 1-aminomethyl-1-cyclohexane acetic acid ("gabapentin") for use in "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." This method of use was claimed in United States Patent No. 4,087,544 (the "epilepsy method patent"). Warner-Lambert is also the assignee of a second method of use patent, United States Patent No. 5,084,479 (the "neurodegenerative method patent"), which covers the treatment of neurodegenerative diseases with gabapentin.[7] Warner-Lambert claimed gabapentin itself in United States Patent No. 4,024,175 (the "product patent").

On April 17, 1998, Apotex filed an ANDA seeking approval to market a generic formulation of gabapentin upon the expiration of Warner-Lambert's epilepsy method patent on January 16, 2000. After Apotex notified Warner-Lambert that it had filed the ANDA and a Paragraph IV certification, Warner-Lambert instituted suit within 45 days in the United States District Court for the Northern District of Illinois. Warner-Lambert alleged that Apotex's submission of an ANDA for gabapentin was an act of infringement of its neurodegenerative method patent under 35 U.S.C. § 271 (e)(2).[8] The district court held that Warner-Lambert was entitled to proceed on an induced infringement theory under 35 U.S.C. § 271(e)(2) and that it was irrelevant whether

---

[7] Epilepsy is not a neurodegenerative disease; therefore, the neurodegenerative method patent does not implicate the use of gabapentin for epilepsy.

[8] The gabapentin patent expired prior to Warner-Lambert's suit.

the asserted method of use patent claimed the use covered by Apotex's ANDA. The court concluded that "[t]he proper inquiry for this Court on the present motion is whether there exists a genuine issue of any material fact as to whether Apotex's gabapentin product, if manufactured, used, or sold, would actively induce the infringement of the '479 patent." *Warner-Lambert Co. v. Apotex Corp.*, 1999 WL 259946, at *3, 1999 U.S. Dist. LEXIS 6208, *10 (N.D.Ill. Apr. 8, 1999). After discovery, the district court entertained motions for summary judgment and concluded that there was no evidence that Apotex actively induced physicians to prescribe its product for neurodegenerative diseases or that Apotex knew its product would be prescribed for neurodegenerative diseases. *Warner-Lambert Co. v. Apotex Corp.*, 2001 WL 1104618, at *3, 2001 U.S. Dist. LEXIS 14592, *8 (N.D.Ill. Sept. 14, 2001). The district court therefore granted Apotex's motion for summary judgment of non-infringement. *Id.* at *4, 2001 U.S. Dist. LEXIS 14592, at *14. Warner-Lambert's appeal to this court followed.

On appeal, the *Warner-Lambert* court expressed concern that permitting a cause of action under section 271(e)(2) for off-label method of use patents would "confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer." *Warner-Lambert*, 316 F.3d at 1359, 65 USPQ2d at 1487. The court also expressed concern about the threat of abuse by a patent holder attempting to extend its patent exclusion. *Id.* Accordingly, the court held that a method of use patent holder may not bring an action under section 271(e)(2) for infringement of a method of use patent that does not claim a FDA-approved use.

The court also determined that "Warner-Lambert would have needed to demonstrate the existence of a genuine issue of material fact to support a traditional infringement claim, *i.e.*, that Apotex induced or will induce infringement of the

neurodegenerative method patent." *Id.* at 1356, 65 USPQ2d at 1485. Upon considering Warner-Lambert's cause of action under section 271(b), the court concluded that "[i]n the absence of any evidence that Apotex has or will promote or encourage doctors to infringe the neurodegenerative method patent, there has been raised no genuine issue of material fact." *Id.* at 1364, 65 USPQ2d at 1491. The court, therefore, affirmed the district court's dismissal of Warner-Lambert's suit.

Under *Warner-Lambert*, Allergan is precluded from suing Alcon and B & L under section 271(e)(2) for inducing infringement of the '415 and '741 patents, because Alcon and B & L are not seeking FDA approval for the uses claimed in the patents and because the uses claimed in the patents are not FDA- approved.[9]

CONCLUSION

For the foregoing reasons, the decision of the district court granting summary judgment in favor of Alcon and B & L is affirmed.

COSTS

Each party shall bear its own costs.

AFFIRMED.

---

[9] Allergan's alternative argument is that section 271(e)(2) provides a direct cause of action that makes an ANDA filer in a case such as this liable for infringement based simply upon the filing of the ANDA. According to Allergan, "[o]n its face, § 271(e)(2)(A) requires that, if a person submits an ANDA for a drug, the use of which is claimed in a patent, in order to engage in the commercial manufacture, use, or sale of the drug, that person has committed an act of infringement." *Warner-Lambert* bars Allergan's direct infringement claim. In any event, *Glaxo* makes it clear that section 271(e)(2) requires proof of all the elements of infringement. *Glaxo*, 110 F.3d at 1567, 42 USPQ2d at 1262 ("The plain language of the statute does not alter a patentee's burden of proving infringement . . . ."). We reject Allergan's contention that section 271(e)(2) acts as a strict liability statute.

SCHALL, Circuit Judge, concurring in the judgment, with whom Circuit Judge CLEVENGER joins.

Because this case is controlled by *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 65 USPQ2d 1481 (Fed. Cir.2003), we must affirm the district court's grant of summary judgment in favor of Alcon and B & L, and I therefore join in the judgment of the court in this case. However, I write separately to express my respectful disagreement with the decision of the court in *Warner-Lambert*.[1] In my view, contrary to the conclusion reached in *Warner-Lambert*, a claim of induced infringement like the one asserted by Allergan against Alcon and B & L is cognizable under 35 U.S.C. § 271(e)(2). I say this for the following reasons:

A. *35 U.S.C. § 271(e)(2)*

Statutory interpretation necessarily begins with the text of the statute. *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438, 119 S.Ct. 755, 142 L.Ed.2d 881 (1999) ("As in any case of statutory construction, our analysis begins with the language of the statute.") (quotations omitted). Our task is to determine whether the statutory language "has a plain and unambiguous meaning with regard to the particular dispute in the case. Our inquiry must cease if the statutory language is unambiguous and 'the statutory scheme is coherent and consistent.'" *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340, 117 S.Ct. 843, 136 L.Ed.2d 808 (1997) (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240, 109 S.Ct. 1026,

[1] Both *Warner-Lambert* and this case were argued and submitted for decision the week of October 7, 2002. When *Warner-Lambert* and this case were argued, the issues they presented were ones of first impression.

103 L.Ed.2d 290 (1989)). I believe the language of 35 U.S.C. § 271(e)(2) is "plain and unambiguous." The statute provides in relevant part as follows:

> (2) It shall be an act of infringement to submit—
>
> (A) an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . .
>
> if the purpose of such submission is to obtain approval under [the FDCA] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2) (emphasis added).

In interpreting a statute, we presume that Congress intended to give words their ordinary meanings. *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187, 115 S.Ct. 788, 130 L.Ed.2d 682, 33 USPQ2d 1430, 1433 (1995). In section 271(e)(2), Congress chose to employ the clause "the use of which is claimed in a patent" in two places. In both places, the words "of which" refer to the word "drug." Thus, Congress did not tie "the use" to the uses stated in the ANDA. Rather, Congress tied "the use" to the uses claimed in the patent. In short, the plain language of section 271(e)(2) compels the conclusion that an action for infringement may lie based upon the filing of an ANDA for a drug whose use is patented, even if approval for the patented use is not sought in the ANDA. 35 U.S.C. § 271(e)(2). Alcon's and B & L's conduct brings them squarely within the language of section 271(e)(2). That is because each has filed an ANDA seeking approval for the commercial sale of a drug (brimonidine) whose use is claimed in two patents that have not yet expired, the '415 patent and the '741 patent.

Alcon argues that an action for infringement of a method of use patent may only be brought under 35 U.S.C. § 271(e)(2)

in the case of a "controlling use patent."[2] Congress was fully aware of the concept of controlling use. See H.R.Rep. No. 98-857, pt. 1, at 22, reprinted in 1984 U.S.C.C.A.N. 2647, 2655. Yet, Congress declined to employ that concept when it wrote section 271(e)(2). *Chicago v. Envtl. Def. Fund*, 511 U.S. 328, 337, 114 S.Ct. 1588, 128 L.Ed.2d 302 (1994) ("But it is the statute, and not the Committee Report, which is the authoritative expression of the law, and the statute prominently *omits* reference to generation.") (emphasis in original).

In order to prevail on a claim of infringement under section 271(e)(2), a patent holder must establish that "if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569, 42 USPQ2d 1257, 1263 (Fed.Cir.1997). That is because section 271(e)(2) "makes it possible for a patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent." *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135, 36 USPQ2d 1641, 1642-43 (Fed.Cir.1995). Consequently, it has been said that when an ANDA filer makes a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii), the patent holder can establish infringement if it shows that the certification "is in error as to whether commercial manufacture, use, or sale of the new drug (none of which has actually occurred) violates the relevant patent." *Eli Lilly Co. v. Medtronic, Inc.*, 496 U.S. 661, 678, 110 S.Ct. 2683, 110 L.Ed.2d 605, 15 USPQ2d 1121, 1130 (1990). Thus, in order to prevail on a claim of induced infringement under section 271(e)(2), a patent holder must establish the traditional elements of a claim of induced infringement. In other words, the patentee must show that, if

---

[2] As explained below, a "controlling use patent" is a patent that claims an indication for a drug for which an ANDA applicant is seeking FDA approval.

the ANDA is approved, the accused infringer will induce a third party to directly infringe the asserted patent and that the accused infringer knows or should know that his actions will induce infringement. *See Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553, 16 USPQ2d 1587, 1594 (Fed.Cir.1990).

Absent *Warner-Lambert*, I would hold that Allergan's claims of induced infringement against Alcon and B & L are cognizable under 35 U.S.C. § 271(e)(2). In that regard, I note what I believe to be the difference between (1) an infringement action involving a method of use patent that claims a use that is the subject of an ANDA and (2) an infringement action involving a patent that claims a use that is not the subject of an ANDA. The only difference between the two types of actions is the degree of proof required. In each case, in order to establish infringement under section 271(e)(2), a patent holder must prove that, upon approval of the ANDA, the ANDA filer will actively induce a third party to directly infringe the asserted patent.[3] *Id.* In the first case, the ANDA filer included a request to use the patented method of use in the ANDA itself. The request in the ANDA is highly probative evidence of likely induced infringement. The ANDA request, however, is just that, evidence. In the second case, a patent holder is not precluded from producing other evidence that also shows induced infringement. As we stated in *Glaxo*, "[t]he plain language of the statute does not . . . mandate an infringement analysis limited to the scope of the approval sought." *Glaxo*, 110 F.3d at 1567, 42 USPQ2d at 1262.

---

[3] A patentee could only allege direct infringement of a method of use patent if the ANDA applicant experimented with or otherwise employed the method of use claimed in the patent and was not protected from infringement by the experimental use exemption granted by the Hatch-Waxman Act. *See* 35 U.S.C. § 271(e)(1).

Under my reading of the statute, Allergan has stated a cause of action for induced infringement under section 271(e)(2) and would have been able to use evidence outside the ANDA itself to show infringement of its patents. It alleges that the '415 and '741 patents will be infringed by doctors who will prescribe Alcon's and B & L's generic brimonidine products for neuroprotection. It also alleges that, with knowledge of the '415 and '741 patents, Alcon and B & L have taken steps to promote brimonidine for neuroprotection. In short, Allergan has asserted a viable claim of induced infringement under 35 U.S.C. § 271(b). The same cannot be said of Warner-Lambert's claim. Even under my reading of the statute, Warner-Lambert's case would have been dismissed and the FDA permitted to approve applicant Apotex's ANDA. Warner-Lambert was not able to present evidence tending to show that Apotex had encouraged, or would encourage, doctors to infringe Warner-Lambert's neurodegenerative method patent.[4]

In my view, Allergan's case is one in which section 271(e)(2) would benefit both the ANDA applicant and the patentee. The ANDA applicant would benefit by challenging the scope of a patentee's rights before the patent expires and before the applicant has invested in production and manufacturing facilities in reliance on its approved ANDA. The patentee, in turn, would profit by enforcing its patent rights before a generic drug manufacturer has moved into the market as a competitor. This balance is what Congress intended when it created the artificial act of infringement

---

[4] The *Warner-Lambert* court stated that "[i]n the absence of any evidence that Apotex has or will promote or encourage doctors to infringe the neurodegenerative method patent, there has been raised no genuine issue of material fact" under section 271(b). *Warner-Lambert*, 316 F.3d at 1364, 65 USPQ2d at 1491.

under section 271(e)(2).[5] In the absence of the section 271(e)(2) mechanism, the owner of a method of use patent claiming an off-label use will bring a section 271(b) induced infringement action, after the ANDA has been approved by the FDA, to enjoin infringement of its patent.

Alcon and B & L point to the fact that an ANDA may not seek approval from the FDA for an unapproved use of a drug.[6] Based upon that fact, they argue that they are precluded by threat of civil and criminal penalties from applying to the FDA to market their generic versions of brimonidine for an unapproved use, such as neuroprotection. I am not persuaded by this argument. The fact that an ANDA may not seek approval from the FDA for an unapproved use of a drug does not mean that section 271(e)(2) fails to create an act of infringement with respect to a patent that claims that unapproved use. It merely suggests that a responsible drug manufacturer will be deterred from marketing a drug for an unapproved use in violation of the law. The threat of a patent infringement suit would further deter a generic drug manufacturer from marketing a generic drug for an off-label patented use and would provide a patentee an enforcement mechanism in the event a generic drug manufacturer violates the law. As I have explained, I believe that section 271(e)(2),

---

[5] These cases do not present a significant threat of abuse by a patent holder attempting to extend its patent exclusion through extensive litigation, because Congress gave district courts the ability to end a party's attempts to delay litigation by controlling the timing of the suit. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (granting the court discretion to change the date on which an ANDA may be approved if "either party to the action failed to reasonably cooperate in expediting the action").

[6] *See* 21 U.S.C. § 355(j)(2)(A)(i) (An ANDA must contain information "to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) . . ."); 21 U.S.C. § 331(d) (prohibited conduct); 21 U.S.C. § 332(a) (injunctions); 21 U.S.C. § 333(a) (criminal penalties); 21 U.S.C. § 334(a)(1) (seizure of the drug).

by its terms, gives a method of use patent owner the right to bring an action for induced infringement based upon a generic drug manufacturer's filing of an ANDA even if the ANDA does not refer to the use claimed in the patent.

B. *21 U.S.C. § 355(b)(1), 21 U.S.C. § 355(j)(2)(A), and 35 U.S.C. § 271(e)(4)*

Alcon and B & L point to (i) 21 U.S.C. § 355(b)(1) (the "Patent Listing Provision"); (ii) 21 U.S.C. § 355(j)(2)(A) (the "Patent Certification Provision"); and (iii) 35 U.S.C. § 271(e)(4) (the "Remedy Provision"). They argue that a correct reading of these statutes undermines the proposition that a method of use patent holder may bring an action under 35 U.S.C. § 271(e)(2) for induced infringement when the patent at issue claims a use for a drug not approved by the FDA and the claimed use is not the use of the drug for which the ANDA filer seeks FDA approval. *See Kokoszka v. Belford*, 417 U.S. 642, 650, 94 S.Ct. 2431, 41 L.Ed.2d 374 (1974) ("When 'interpreting a statute, the court will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute . . . and the objects and policy of the law . . . and give to it such a construction as will carry into execution the will of the Legislature . . . .'") (quoting *Brown v. Duchesne*, 19 How. 183, 194, 15 L.Ed. 595 (1857)). I address these contentions in turn.

(i) *The Patent Listing Provision, 21 U.S.C. § 355(b)(1)*

The Patent Listing Provision provides in pertinent part as follows:

> The applicant shall file with the [NDA] the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed

> by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1) (emphasis added).[7] Alcon and B & L assert that, as far as method of use patents are concerned, a NDA applicant may only file the patent number and expiration date ("patent information") for patents that claim uses that are stated in the NDA. They also argue that a successful NDA applicant must seek to have removed from the Orange Book any patent that does not claim a use for which the NDA is approved.[8] Accordingly, Alcon and B & L contend that Allergan, as the NDA holder for brimonidine, improperly obtained the listing of its method of use patents in the Orange Book because the neuroprotective function of brimonidine is not an indication for brimonidine that has been approved by the FDA. Allergan responds that the Patent Listing Provision does not limit the method of use patents that should be listed in the Orange Book to only those method of use patents that cover uses approved through the NDA process.

In my view, Allergan's reading of the statute is true to its words. First, Congress chose to include the word "any" before "patent." Congress thus required that "*any* patent . . . which claims a method of using such drug . . ." must be listed. 21 U.S.C. § 355(b)(1) (emphasis added). Second, in the part of the statute that states "[t]he applicant shall file with the [NDA] the patent number and the expiration date of any patent which claims the drug for which the applicant

---

[7] The holder of an approved NDA is required to provide the patent number and expiration date of similar method of use patents that are issued after the date the NDA is approved. *See* 21 U.S.C. § 355(c)(2).

[8] This court has held that "a generic drug manufacturer cannot bring a declaratory judgment action or an injunctive action against a NDA holder under either the [FDCA] or the patent laws requiring it to take steps to 'delist' a patent from the Orange Book." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1373-74, 61 USPQ2d 1414, 1417 (Fed.Cir.2002).

submitted the application," the word "drug" is followed by the words "for which the applicant submitted the application." *Id.* However, the "or which claims a method of using" language of the statute, which immediately follows, contains no limitation that the method of using the drug be contained in the NDA. I believe the meaning of the statutory language is plain and unambiguous. A pharmaceutical manufacturer, such as Allergan, who holds an approved NDA for a drug is required to provide patent information for listing in the Orange Book for any patent which claims a method of using the approved drug that is issued after the NDA is approved.

It is a concept of general patent law under 35 U.S.C. § 271(b) that the owner of a method of use patent may assert a claim of induced infringement if a third party, not licensed by the owner of the patent, engages in the patented use due to the active inducement of a product manufacturer. *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus.*, 145 F.3d 1303, 1311, 46 USPQ2d 1752, 1759 (advertisements to customers encouraging infringing use were sufficient to support claim of induced infringement). This concept supports the general purpose of the Patent Listing Provision, which is to give notice to a potential infringer (direct or induced) of patents upon which the patentee could reasonably bring a suit. Moreover, in *Eli Lilly*, the Supreme Court described the Patent Listing Provision requirement as follows: "Pioneer drug applicants are required to file with the FDA the number and expiration date of any patent which claims . . . a method of using such drug." *Eli Lilly*, 496 U.S. at 677, 110 S.Ct. 2683, 15 USPQ2d at 1129 (emphasis added). The Court described the statute in terms that did not limit its application to only those patented methods of using the drug that are approved by the FDA. *Id.*

Alcon also points to the FDA regulation that implements the Patent Listing Provision, 21 C.F.R. § 314.53(b).[9] Specifically, Alcon relies on the part of the regulation that states: "For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application." 21 C.F.R. § 314.53(b) (emphasis added). Alcon argues that this means that only method of use patents claiming uses that have been approved by the FDA may be submitted for listing in the Orange Book. Allergan, on the other hand, reads section 314.53(b) as requiring the listing of patents, such as the '415 patent and the '741 patent, that claim "other conditions of use," such as a neuroprotective use for brimonidine, for a drug that is the subject of a NDA or an approved NDA. In short, Allergan urges that section 314.53(b) does not limit the broad language of 21 U.S.C. § 355(b)(1). I agree.

I note at the outset that Alcon's reading of the regulation is inconsistent with the clear language of 21 U.S.C. § 355(b)(1), which I have just examined. *See Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 484, 121 S.Ct. 903, 149 L.Ed.2d 1 (2001) (rejecting an agency's interpretation of a statutory requirement because the interpretation was at odds with the "structure and manifest purpose" of the statute). A court is properly reluctant to embrace a reading of a regulation that makes the regulation conflict with the statute that it is meant to implement. *See Gomez v. Dept. of Air Force*, 869 F.2d 852, 858 (5th Cir.1989) ("[W]e are compelled to interpret the regulation in accordance with Title VII because it is the governing statute.").

As I read section 314.53(b), Allergan was required to provide information for the Orange Book for any method of

---

[9] All references are to regulations as set forth in the 2002 version of the Code of Federal Regulations.

use patents it held that claimed "indications or other conditions of use of a pending or approved application." The '415 and '741 patents were covered by the language of the regulation because they claimed "other conditions of use" (the use of brimonidine for neuroprotection) of a "pending or approved application" (Allergan's approved NDA application for brimonidine).[10] In short, I see nothing in the Patent Listing Provision that supports the argument that Allergan is barred from asserting its claim of induced infringement against Alcon and B & L.[11]

---

[10] The regulation that governs the content and format of NDAs is set forth at 21 C.F.R. § 314.50. The regulation indicates that the FDA distinguishes between a drug product's proposed indications of use and other uses of the drug product. *Compare* 21 C.F.R. § 314.50(a)(1) (requiring submission of the drug product's "proposed indications for use") with 21 C.F.R. § 314.50(d)(5)(iv) (requiring submission of "relevant" clinical data concerning "uses of the drug other than those proposed in the application").

[11] On October 24, 2002, the FDA issue a proposed rule that would, among other things, amend 21 C.F.R. § 314.53(b). *See* Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not be Infringed, 67 Fed.Reg. 65,448 (proposed October 24, 2002). Under the proposed rule, the part of section 314.53(b) that speaks to method of use patents would be amended to read as follows:

> For patents that claim a method of use, the [NDA] applicant shall submit information only on those patents that claim indications or other conditions of use that are the subject of a pending or approved application.

67 Fed.Reg. at 65,451 (emphasis added).

Alcon and B & L argue that the FDA's proposed rule supports their contention that so-called "off-label" use patents—patents such as the '415 and '741 patents that claim unapproved uses of a drug—"were not intended to serve as the basis for an action under 35 U.S.C. § 271(e)(2)." Allergan responds that the "perceived need of FDA to change its current regulation indicates that the current regulation permits the listing of all

(ii) *The Patent Certification Provision, 21 U.S.C. § 355(j)(2)(A)*

The Patent Certification Provision provides in pertinent part as follows:

> An [ANDA] shall contain—
>
> (i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");
>
> * * *
>
> (vii) a certification . . . with respect to each patent which claims the listed drug . . . or which claims a *use* for such *listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section*—
>
> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, or

---

method of use patents concerning an approved drug whether or not the use is approved."

I am reluctant to look to a notice of proposed rule making as a tool of statutory construction. *See Commodity Futures Trading Comm'n v. Schor,* 478 U.S. 833, 845, 106 S.Ct. 3245, 92 L.Ed.2d 675 (1986) ("It goes without saying that a proposed regulation does not represent an agency's considered interpretation of its statute and that an agency is entitled to consider alternative interpretations before settling on the view it considers most sound."). In any event, having concluded that under the plain language of 21 U.S.C. § 355(b)(1), Allergan was required to provide patent information for the '415 patent and '741 patent when the patents issued, I would not construe the language of the proposed amended version of section 314.53(b). *See Whitman,* 531 U.S. at 484, 121 S.Ct. 903; *Gomez,* 869 F.2d at 858.

> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and
>
> (viii) if with respect to the listed drug referred to in clause (i) information was filed under [the Patent Listing Provision] for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

21 U.S.C. § 355(j)(2)(A) (emphasis added).

Alcon and B & L contend that the words "for which the applicant is seeking approval under this subsection" in clause (vii) refer to the term "use," not "listed drug." Therefore, they argue, an ANDA filer is not required to make a Paragraph IV certification with respect to a method of use patent that does not claim a use for which the ANDA filer is seeking FDA approval. Alcon and B & L reason that this demonstrates that section 271(e)(2) was not meant to support a claim of induced infringement such as the one advanced by Allergan. Allergan argues the contrary, stating that the phrase at issue modifies "listed drug," not "use."

As a matter of statutory interpretation, I believe Allergan is correct. There are two parallel "for which" clauses in the Patent Certification Provision: "for which the applicant is seeking approval under this subsection" and "for which information is required to be filed under subsection (b) or (c) of this section." The references in the second clause to "subsections (b) and (c) of this section" are to 21 U.S.C. § 355(b) and 21 U.S.C. § 355(c), respectively. As already discussed, these subsections require the NDA filer or the holder of an approved NDA to submit for listing in the Orange Book specified information with respect to the drug, including "any patent which claims . . . a method of using [the drug covered by the NDA] and with respect to which a claim of patent infringement could reasonably be asserted if a person not

licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§ 355(b)(1) and 355(c)(2). The second clause, therefore, must modify "listed drug." Since the first "for which" clause is parallel to the second, it must also modify "listed drug." Moreover, the first clause is subject to the restriction "under this subsection." 21 U.S.C. § 355(j)(2)(A)(vii). Subsection 355(j) deals with the filing of ANDAs for new drugs, stating that "[a]ny person may file with the Secretary an abbreviated application for the approval of a new drug." 21 U.S.C. § 355(j)(1). In my view, this supports the parallel construction of the sentence and confirms that the phrase disputed by Allergan and Alcon modifies the term "listed drug," as Allergan suggests. Therefore, I conclude that the Patent Certification Provision does not alter the plain meaning of 35 U.S.C. § 271(e)(2).

Alcon and B & L cite the legislative history of the Hatch-Waxman Act concerning the Patent Certification Provision for the proposition that an ANDA applicant need not make a Paragraph IV certification with respect to a patent that claims a method of using a drug for which the ANDA does not seek approval. The legislative history states in relevant part as follows:

> . . . [A]n ANDA must include a certification by the applicant regarding the status of certain patents applicable to the listed drug if the patent information has been submitted under section 505(b) or (c). With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval (hereinafter described as a *controlling use patent*), the applicant must certify, in his opinion and to the best of his knowledge, as to one of four circumstances.
>
> * * *
>
> If appropriate, the applicant may certify that one or more of the product or *controlling use patents* provided have expired . . . . [A]n applicant may certify if applicable

> that one or more of the product or *controlling use patents* are invalid or will not be infringed.
>
> The committee recognizes that in some instances an applicant will have to make multiple certifications with respect to product or *controlling use patents.* For example, if the product patent has expired and a valid *controlling use patent* will not expire for three years, then the applicant must certify that one patent has expired and the other will expire in three years. The committee intends that the applicant make the appropriate certification for each product and *controlling use patent.*

H.R.Rep. No. 98-857, pt. 1, at 22, reprinted in 1984 U.S.C.C.A.N. 2647, 2655 (emphasis added).

Alcon and B & L urge that the material quoted from the House Report demonstrates that a claim of infringement under 35 U.S.C. § 271(e)(2) may, in the case of a method of use patent, only be brought if the ANDA filer seeks approval for the use claimed in the patent. I do not agree. The legislative history states that "controlling use patents" include "all use patents which claim an indication for the drug for which the applicant is seeking approval," while section 355(j)(2)(A) requires "a certification . . . with respect to each patent . . . which claims a use for such listed drug for which the applicant is seeking approval." The language that must be interpreted in the statute is virtually the same as the language that appears in the House Report. Under these circumstances, one might say that the legislative history, in fact, is no narrower than section 355(j)(2)(A) and can be interpreted consistently.

In any event, Alcon's and B & L's reading of the phrase "controlling use patent" leads to an interpretation of the Patent Certification Provision that is inconsistent with what I have just concluded is the plain meaning of the statute. Given its near symmetry with the language of the statute, I do not believe the statement from the House Report upon which

Alcon and B & L rely is sufficient to overcome this plain meaning, and therefore, alter the Patent Certification Provision requirement. *Garcia v. United States*, 469 U.S. 70, 75, 105 S.Ct. 479, 83 L.Ed.2d 472 (1984) ("[O]nly the most extraordinary showing of contrary intentions from [the legislative history] would justify a limitation on the "plain meaning" of the statutory language."). I conclude that the legislative history relating to the Patent Certification Provision does not assist Alcon and B & L in their interpretation of section 271(e)(2).

Additionally, the Patent Listing Provision, discussed in section (B)(i) *supra*, requires a NDA holder to submit to the FDA for listing in the Orange Book all patents that claim a method of using the approved drug "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). In my view, a distorted interpretation of the Patent Certification Provision results if one does not interpret 21 U.S.C. § 355(j)(2)(A) to require an ANDA filer to make a Paragraph IV certification for a method of use patent listed in the Orange Book with respect to which a claim of patent infringement could reasonably be asserted against the filer, even if the filer did not seek approval for the patented use in the ANDA. This is especially true because many patentees look to the Paragraph IV certification for error when establishing a claim of infringement under 35 U.S.C. § 271(e)(2). *See Eli Lilly*, 496 U.S. at 678, 110 S.Ct. 2683, 110 L.Ed.2d 605, 15 USPQ2d at 1130. Accordingly, I believe that an ANDA applicant must make a Paragraph IV certification for each listed patent that claims the drug included in the ANDA and for each listed method of use patent related to that drug that could form the basis for a claim of infringement.[12]

---

[12] If a patent is not listed in the Orange Book, a Paragraph I certification may be appropriate.

I agree with Alcon and B & L that Congress intended a generic drug manufacturer to be able to gain approval from the FDA to manufacture and market an unpatented drug for a use that is not covered by a patent. Both 21 U.S.C. § 355(j)(2)(A)(viii) and the example in House Report 98-857 suggest that this is the case. Section 355(j)(2)(A)(viii) requires an ANDA filer to state that it is not applying for the patented use. The example in the House Report illustrates this concept and states as follows: "For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for indication No. 1, and not indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for indication No. 2." H.R. Rep. No. 98-857, pt. 1, at 22-23 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48. However, I do not share the conclusion that Alcon and B & L draw from the language of section 355(j)(2)(A)(viii) and from the example in the House Report; namely that Congress intended a patent holder to be without recourse when a generic drug manufacturer will induce a third party to infringe a method of use patent upon approval of an ANDA. I believe the conclusion is at odds with the plain language of 35 U.S.C. § 271(e)(2). In addition, as the Supreme Court stated in *Eli Lilly*, "[the ANDA] scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement." *Eli Lilly*, 496 U.S. at 678, 110 S.Ct. 2683, 110 L.Ed.2d 605, 15 USPQ2d at 1130.

(iii) *The Remedy Provision, 35 U.S.C. § 271(e)(4)*

Finally, Alcon and B & L argue that the exclusive remedies of 35 U.S.C. § 271(e)(4) are particularly severe in a case where an ANDA filer is seeking approval for the production of an unpatented drug for an unpatented use. From that point, they contend that Congress could only have meant those

remedies to apply in the case of a method of use patent that claims an approved use of a drug for which the ANDA filer seeks approval, and that, therefore, the reach of section 271(e)(2) must be limited to such patents. The Remedy Provision of section 271(e)(4) states in relevant part as follows:

> (4) For an act of infringement described in paragraph (2)—
>
> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . ., and
>
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug. . . .
>
> The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2). . . .

35 U.S.C. § 271(e)(4). I do not think that Alcon's and B & L's argument that the remedies provided in section 271(e)(4) are extreme in the situation where there is a determination of induced infringement under 35 U.S.C. § 271(e)(2) is sufficient to override the plain language of the statute. It is within the purview of Congress to fashion remedies in the manner it deems appropriate. The Remedy Provision does not require that section 271(e)(2) be limited to

method of use patents that claim an approved use of a drug for which the ANDA filer seeks approval.

I do note, however, that Alcon's and B & L's arguments concerning the Remedy Provision bring into focus the fact that, to a large extent, their contentions in this case are grounded in policy considerations. It is the view of Alcon and B & L and the holding of *Warner-Lambert* that a method of use patent holder, such as Allergan, should not be able to bring an action for induced infringement under 35 U.S.C. § 271(e)(2) against a generic drug manufacturer who submits an ANDA seeking approval to market a drug for an approved, non-patented use that is different from the unapproved use for the same drug that is claimed in the method of use patent. I conclude, however, that the language of section 271(e)(2) and the overall statutory scheme of the Hatch-Waxman Act do not bar such an action.

If Congress determines that the owner of a method of use patent should not have an action for induced infringement against an ANDA filer in the circumstances that exist in this case, or that a more lenient injunctive remedy should be available for infringers of such method of use patents, it can amend section 271(e)(2) or section 271(e)(4) so as to compel a result different from the one I would reach. *See Reid v. Dep't of Commerce*, 793 F.2d 277, 284 (Fed.Cir.1986) ("'The remedy for any dissatisfaction with the results in particular cases lies with Congress' and not with this court. 'Congress may amend the statute; we may not.'") (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 576, 102 S.Ct. 3245, 73 L.Ed.2d 973 (1982)). However, until Congress takes such action, I believe we must apply the statute as written.

For the foregoing reasons, I respectfully disagree with the decision of the court in *Warner-Lambert*. I would hold that 35 U.S.C. § 271(e)(2) may serve as the basis for an infringement action with respect to a method of use patent for an off-

label use, when the patentee can prove that an ANDA applicant applying for the right to manufacture, use, or sell a drug actively encourages doctors and/or patients to use the generic version of the drug for the patented off-label use once the ANDA is approved. As a result, were I free to do so, I would reverse the decision of the district court and would remand the case in order to allow Allergan's suit for induced infringement under section 271(e)(2) to proceed.[13]

---

[13] As noted in the per curiam opinion, the district court found that, as far as Allergan's claim of induced infringement against Alcon was concerned, the record before the court was sufficient to present a triable issue of fact or, at the least, was sufficient to permit Allergan to conduct discovery under Fed.R.Civ.P. 56(f). In its motion for summary judgment, B & L argued that Allergan could raise no triable issue of fact regarding whether, if its ANDA were approved, B & L would induce infringement of the '415 and '741 patents. In granting Alcon's and B & L's motions for summary judgment, the district court did not address B & L's contention that Allergan could not establish a genuine issue of material fact with respect to B & L's alleged inducing of infringement. On remand, the district court would have the opportunity to consider this issue.

LINN, Circuit Judge, concurring in the judgment.

I concur in the conclusion of the panel that this case is controlled by *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed.Cir.2003). I also agree that it is reasonable, as a matter of patent policy, to conclude, as the *Warner-Lambert* panel did, that it should not be "an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA." *Id.* at 1354-55. I write separately to express my disagreement not with the logical conclusions reached by the court in *Warner-Lambert* but with the court's looking beyond the congressional intent expressed in the plain meaning of the statute to reach those conclusions. In my opinion, the court in *Warner-Lambert* has ventured beyond our interpretive role and, in interpreting the complex statutory scheme before it, has allowed its policy choices and its evaluation of the legislative history—reasonable as they may be—to override the terms of the statute chosen by Congress.

While the statutory scheme forming the basis for an ANDA filing is hardly a model of clarity, *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 679, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990), 35 U.S.C. § 271(e)(2) is itself not grammatically complex. It simply states that "[i]t shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent." The normal reading of "the use" in this context is simply "any use." This is also consistent with the surrounding provisions of the Hatch-Waxman Act, as carefully described in Judge Schall's concurring opinion. There is no indication that Congress deliberately selected the definite article in order to restrict the scope of the term to a use already approved by the FDA. Rather, the language employed is simply the natural way to express the concept

that the filing of an ANDA to produce a drug having a patented use is an act of infringement. In such cases, our judicial role is to follow the plain meaning of the particular provision at issue, even if there are policy concerns that could be addressed by declining to adhere to the strict literal terms of the statutory language Congress has employed. *See Fed. Bureau of Investigation v. Abramson*, 456 U.S. 615, 633, 102 S.Ct. 2054, 72 L.Ed.2d 376 (1982) (O'Connor, J., dissenting) ("A judge must not rewrite a statute, neither to enlarge nor to contract it. Whatever temptations the statesmanship of policy-making might wisely suggest, construction must eschew interpolation and evisceration.") (*quoting* Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 Colum. L.Rev. 527, 533 (1947)).

In effect, the court in *Warner-Lambert* reads the words "the use for which the FDA has granted an NDA" into the statute, concluding that "it is clear that the phrase 'the use' in § 271(e)(2)(A) refers to the use for which the FDA has granted an NDA." *Warner-Lambert*, 316 F.3d at 1356. Moreover, the opinion discusses the purposes of the Hatch-Waxman Act and concludes that a broader interpretation of section 271(e)(2) would lead to undesirable consequences:

> Warner-Lambert's proposed interpretation [that "the use" means "any use"] is inconsistent with both of the stated purposes of the Hatch-Waxman Act, and would confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer. If Warner-Lambert's interpretation were correct, for example, an NDA holder would be able to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its NDA. It would then be able to use § 271(e)(2)(A) as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent. Generic

> manufacturers would effectively be barred altogether from entering the market.

Warner-Lambert, 316 F.3d at 1359. However compelling such arguments may be, it is the function of Congress, not the courts, to shape legislation in accordance with policy goals. "Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy." *United States v. Rutherford*, 442 U.S. 544, 555, 99 S.Ct. 2470, 61 L.Ed.2d 68 (1979). *See also Artuz v. Bennett*, 531 U.S. 4, 10, 121 S.Ct. 361, 148 L.Ed.2d 213 (2000) ("Whatever merits these and other policy arguments may have, it is not the province of this Court to rewrite the statute to accommodate them."); *Badaracco v. Comm'r of Internal Revenue*, 464 U.S. 386, 398, 104 S.Ct. 756, 78 L.Ed.2d 549 (1984) ("Courts are not authorized to rewrite a statute because they might deem its effects susceptible of improvement."); *Bankamerica Corp. v. United States*, 462 U.S. 122, 140, 103 S.Ct. 2266, 76 L.Ed.2d 456 (1983) ("[W]e are not to rewrite the statute based on our notions of appropriate policy.").

It is for Congress, not this court, to explain why the intent expressed in the plain meaning of the language used in section 271(e)(2) does not reflect its intent as to the policy governing applications by generic drug manufacturers to produce drugs that may have patented "off-label" uses. *See Blount v. Rizzi*, 400 U.S. 410, 419, 91 S.Ct. 423, 27 L.Ed.2d 498 (1971) ("[I]t is for Congress, not this Court, to rewrite the statute."). The importance of this issue suggests that Congress consider revisiting the terms of the Hatch-Waxman Act to clarify or confirm its intent. In the absence of any congressional action to that end, I would interpret the statute as set forth in Judge Schall's concurring opinion if I were not bound to follow the precedent of our *Warner-Lambert* decision.

APPENDIX B

UNITED STATES DISTRICT COURT
C.D. CALIFORNIA

No. SA CV 02-40 DOC.

ALLERGAN, INC.; Allergan Sales, Inc.,
Plaintiffs,

v.

ALCON LABORATORIES, INC.; Alcon Research, Ltd.; Alcon Universal, Ltd.; Bausch & Lomb, Inc.,
Defendants.

May 8, 2002.

ORDER GRANTING ALCON DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

CARTER, District Judge.

Before the Court is Defendants' Alcon Laboratories, Inc., Alcon Research, Ltd., and Alcon Universal, Ltd.'s (collectively Alcon) motion for summary judgment on Plaintiffs' Allergan, Inc. and Allergan Sales, Inc.'s (collectively Allergan) complaint for patent infringement. After reviewing the moving, opposing, and replying papers, after oral argument on April 29, 2002, and for the reasons set forth below, the Court GRANTS Alcon's motion.

I.

BACKGROUND

A. Glaucoma

Open-angle glaucoma, the most common form of glaucoma, is a disease of the eye that leads to a gradual loss of

vision. Glaucoma is caused by damage to optical cells. As those cells are damaged, vision becomes impaired. Generally, individuals that suffer from glaucoma lose their peripheral vision and subsequently develop blind spots at the sides. If not arrested, it may lead to blindness. Risk factors for glaucoma have traditionally included people with diabetes, high blood pressure, near sightedness, a family history of glaucoma, and black and elderly people. Treatment at the early stages of glaucoma is important because damaged cells cannot be repaired.

The human eye works when light enters through the cornea, passes through the pupil, and then travels through the lens and the vitreous body to the retina and the optic nerve. The optic nerve then carries the images to the brain for interpretation. The eye produces a watery fluid called aqueous humor that nourishes the eye's internal structures. Aqueous humor is continuously produced and drained between the lens and the vitreous body. When the drainage does not keep up with the production, the fluid backs up causing increased pressure in the eye, called intraocular pressure (IOP). For decades, the traditional view of the medical profession was that glaucoma was caused by an abnormally high IOP, which pushed against the optic nerve causing it to be damaged. Treatment for glaucoma thus consisted of reducing IOP.

Research has shown that the drug brimonidine, sold by Allergan under the trade name Alphagan®, reduces IOP. Alphagan® therefore became a leading drug to treat glaucoma.

In recent years, however, the medical science view of glaucoma has changed. Scientists discovered that patients with lower IOP's were still contracting glaucoma. Some evidence has since shown that the disease may originate from the optic nerve itself. Scientists are now increasingly thinking of glaucoma as a neurodegenerative disease.

In the early 1990's, Allergan scientists discovered that brimonidine had neuroprotective properties such that applying it to nerve cells make them less susceptible to injury and degeneration than those not treated with brimonidine. Thus, Alphagan® may be a potent treatment for glaucoma as a neuroprotective agent under this new view of the disease.

B. New Drug and Generic Drug Application Procedures

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, was adopted by Congress to address the need to bring generic drugs to the market quickly and changed the way in which the Food and Drug Administration (FDA) approved the manufacture and use of new and generic drugs. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed.Cir.1997). One of the most important aspects of the Hatch-Waxman Act was to "make available more low cost generic drugs." *Id.* (quoting H.R.Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48).

In order to market a new drug, the maker of the drug must obtain approval from the FDA. 21 U.S.C. § 355(a). In order to obtain FDA approval, the maker must submit a New Drug Application (NDA) which includes extensive information and testing of the new drug to insure its safety. See 21 U.S.C. § 355(b). Once the NDA is approved, the holder of an approved NDA is automatically granted a five-year period of exclusivity in marketing its drug. 21 U.S.C. § 355(c)(3)(D)(ii). That period of exclusivity is extended by an additional six months if the maker conducts certain tests to insure its safety and efficacy in children. 21 U.S.C. § 355a(a)(1)(i). During this period of exclusivity, the FDA may not grant any other drug maker a license to manufacture and sell the same drug or its bioequivalent. This period of exclusivity is intended to recognize the efforts and costs that the drug maker undertook in the first place to test and insure the safety and efficacy of a new, or pioneer, drug.

Near the end of that period of exclusivity, a drug maker may file an Abbreviated New Drug Application (ANDA). *See* 21 U.S.C. § 355(j). A party submitting an ANDA need only show that the proposed new drug is the same, or the bioequivalent, of the pioneer drug.

During the ANDA process, a generic drug maker must certify that the pioneer drug is either: (i) not patented (Paragraph I Certification); (ii) protected by a patent that has expired (Paragraph II Certification); (iii) patented, but setting forth the date the patent will expire (Paragraph III Certification); or (iv) that the pioneer drug's patent is either expired or will not be infringed by the generic drug (Paragraph IV Certification). *See* 21 U.S.C. § 355(j)(2)(A)(vii). An ANDA with either Paragraph I or II certification may be quickly approved and marketed as soon as all regulatory requirements are met. An ANDA with Paragraph III Certification may not be approved until the relevant patents have expired.

Paragraph IV Certification, however, creates a different set of procedures. Under Section 202 of the Hatch-Waxman Act, Congress has specifically exempted a party that uses a patent in order to prepare an application for commercial marketing of a drug from liability for infringement. 35 U.S.C. § 271(e)(1). However, the submission of an ANDA is an act of infringement. 35 U.S.C. § 271(e)(2)(A). This infringement is "highly artificial." *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 110 S.Ct. 2683, 2691, 110 L.Ed.2d 605 (1990). Congress enacted this statutory scheme in order to allow generic drugs to come to the market as quickly as possible. *See id.* By allowing a generic drug maker to use the patent as it prepares to obtain FDA approval, the drug maker can bring the generic drug to market as soon as the patent expires, rather than waiting for the patent to expire before undertaking years of regulatory hurdles. By the same token, allowing the filing of the ANDA to amount to an act of

infringement, the validity of a patent can be challenged before the drug comes to market. A party submitting an ANDA with a Paragraph IV Certification must inform the drug and patent owner of the application. *See* 21 U.S.C. § 355(j)(2)(B)(i). The patent owner then has 45 days in which to file an action for infringement, the basis of which is the "artificial" act of infringement of filing an ANDA. If the patent-holder does not sue for infringement, the ANDA may be quickly approved and marketed as soon as all regulatory requirements are met. If the patent-holder does file suit, the ANDA may not be approved until either the date that the Court determines either invalidity or non-infringement, the date the patent expires, or 30 months (subject to modification by the Court) after the ANDA patent holder receives notice of the Paragraph IV Certification.

C. Allergan's NDA for Alphagan® (Brimonidine)

On September 6, 1996, Allergan obtained FDA approval of its NDA, granting approval for the manufacture and sale of Alphagan® for reducing IOP, in accordance with a specific set of labeling instructions. Allergan was entitled to a five year period of exclusivity under 21 U.S.C. § 355(c)(3)(D)(ii) and an additional six month period under 21 U.S.C. § 355a(a)(1)(i). Brimonidine, however, was not protected by a patent, and thus Allergan's period of exclusivity was originally set to expire March 6, 2002.

Before that time elapsed, however, Allergan scientists discovered the neuroprotective properties of brimonidine. Accordingly, in 1999 and 2000, Allergan applied for patents covering this new use of brimonidine. In 2001, Allergan was granted U.S. Patents Nos. 6,194,415 (the '415 Patent) and 6,248,741 (the '741 Patent), both of which are continuations in part of U.S. Patent No. 5,856,329 (the '329 Patent).

The '415 and the '741 Patents (the patents at issue in this case) both claim a method of using brimonidine for treating

ocular neural injury. During the prosecution of the patents at issue, Allergan initially attempted to claim the use of brimonidine to reduce IOP. The patent examiner rejected those claims as being obvious. Allergan then limited its claims to a method of using brimonidine as a neuroprotective agent to treat glaucoma. Allergan then listed the patents in the "Orange Book," a record maintained by the FDA to provide notice to manufacturers of generic drugs that the maker of an approved new drug claims that the drug is also protected under the patent laws.[1]

In October 2001, Alcon filed an ANDA with the FDA, seeking to sell a generic brimonidine solution for use in reducing IOP with the same FDA labeling requirements approved for Alphagan®. Because the '415 and the '741 Patents were both listed in the Orange Book, Alcon filed a Paragraph IV Certification claiming that its drug was non-infringing or that the patents were invalid. Alcon notified Allergan on November 29, 2001 and Allergan brought suit within the statutorily required 45 days on January 9, 2002. Alcon now moves for summary judgment based on its argument that its proposed generic drug, labeled for use as an IOP reducing agent, but not as a neuroprotective agent, does not infringe the patents at issue.

The result of listing the '415 and '741 Patents in the Orange Book was obviously advantageous to Allergan. Under the terms of its NDA approval, its five year period of exclusivity for the sale of brimonidine under the name Alphagan® would have expired in March 2002. If, however, it can successfully claim protection under the Patent Act, it will be able to retain exclusive rights to brimonidine for the twenty year period prescribed under the Patent Act, through

---

[1] Listing in the "Orange Book" is entitled to no presumption about the validity of the drug or patent owner's claims, and is a ministerial act on the part of the FDA. *See Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F.Supp.2d 446, 456 (D.N.J.1998).

2015. If successful in this litigation, Allergan will retain the exclusive rights to manufacture brimonidine, even when the proposed use by Alcon is for reduction of IOP. Allergan will effectively be able to retain the exclusive rights to use brimonidine for a purpose that the Patent Office determined that it could not patent.

II.

LEGAL STANDARD

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c).

The Court must view the facts and draw inferences in the manner most favorable to the non-moving party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655, 82 S.Ct. 993, 994, 8 L.Ed.2d 176 (1962). However, the existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; to defeat the motion, the non-moving party must affirmatively set forth facts showing there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202 (1986). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact for trial. *Id.* at 256, 106 S.Ct. at 2514. When the non-moving party bears the burden of proving the claim or defense, the moving party can meet its burden by pointing out the absence of evidence of a genuine issue of material fact from the non-moving party. *Vivid Techs., Inc. v. Am. Science & Eng'g, Inc.*, 200 F.3d 795, 806-07 (Fed.Cir.1999). The moving party need not disprove the other party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25, 106 S.Ct. 2548, 2553-54, 91 L.Ed.2d 265 (1986).

When the moving party meets its burden, the "adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party." Fed.R.Civ.P. 56(e). "The mere existence of a scintilla of evidence . . . will be insufficient; there must be evidence on which the jury could reasonably find for [the opposing party]." *Anderson*, 477 U.S. at 252, 106 S.Ct. at 2512.

III.

DISCUSSION

A. Elements of Infringement

Determining whether there is infringement in a case requires a two step analysis. *Glaxo*, 110 F.3d at 1565. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1576, (Fed.Cir.1993). Claim construction is a question of law for the Court to determine in the first instance. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-81 (Fed.Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Once the claim is properly construed, determining whether a particular device infringes the patent is a question of fact. *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1569 (Fed.Cir.1983). To prove infringement, a patentee must show that every limitation of the claims asserted to be infringed is found in the accused device. *Glaxo*, 110 F.3d at 1565.

B. Claim Construction

Here, there is no material dispute as to the claims of the patents at issue. Both sides agree that the patents at issue claim the neuroprotective use of brimonidine, but not its use to reduce IOP.[2]

C. Infringement Under Section 271(e)(2)

"Allergan contends that defendants have and will infringe at least Claim 2 of the '415 patent and Claim 1 of the '741 patent." (Allergan's Mem. of P. & A. in Opp'n to Mot. for Summ. J. at 5.) Allergan's assertions of infringement are twofold. First, Allergan argues that by filing the ANDA, Alcon has committed infringement under Section 271(e)(2)(A). Second, Allergan argues that Alcon will induce infringement by doctors prescribing generic brimonidine in violation of 35 U.S.C. § 271(b).

The primary question presented in this motion is whether Allergan can, as a matter of law, bring either of these claims at this time. If it can, the record currently before the Court is sufficient to present a triable issue of fact, or at the least, allow Allergan to conduct discovery under Federal Rule of Civil Procedure 56(f) before its claim is adjudicated.

This question of law, however, is one of nearly first impression. The Court is aware of only two cases in the country, neither reported, that have squarely addressed the issue of whether a holder of a patent for a method of using a drug in the public domain can sue a generic manufacturer for infringement based solely on filing an ANDA under Section 271(e). *See Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293, 1999 WL 259946 (N.D.Ill. Apr.8, 1999); *see also In re*

---

[2] Allergan argues that the patents at issue do not claim the use of brimonidine *solely* to reduce IOP. Although the Court does not interpret the claim in that manner, the distinction is ultimately immaterial for disposition of the present motion.

Omeprazole Patent Litigation, MDL Docket No. 1291 (S.D.N.Y. July 2, 2001) (Slip op. at 25). The problem is made worse by the somewhat awkward wording of the statute. Indeed, the Supreme Court has stated that "[n]o interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship." *Eli Lilly,* 496 U.S. at 679, 110 S.Ct. at 2693. Therefore, to fully understand the extent of Section 271(e), a brief review of its history and purpose are appropriate.

1. Legislative Background of the Hatch-Waxman Act and Section 271(e)(2)

The Hatch-Waxman Act encompassed two different legislative issues that developed during the late 1970's. The first problem addressed by the bill was a method for bringing popular generic drugs to the market more quickly. H.R. Rep. No. 98-857(I) at 14, 1984 U.S.C.C.A.N. at 2647. The regulatory delay in bringing new generic drugs to the market keeps drug prices artificially high. The higher prices had particularly negative affects on senior citizens and drove up the cost of federal medicare and medicaid programs. *Id.* at 19-21, 1984 U.S.C.C.A.N. at 2652-53. As early as 1978, the FDA had considered regulatory action to allow for some abbreviated application. *Id.* at 16, 1984 U.S.C.C.A.N. at 2649. After several years of waiting, Congress took action itself just prior to the 1984 Presidential Election.

The Hatch-Waxman Act also responded to complaints by patent owners that the patent term for certain products, such as drugs, was effectively eroded because patent holders could not exploit their inventions while the drugs went through the long period of regulatory approval. H.R.Rep. No. 98-857(II) at 3 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2687; *see also Eli Lilly*, 496 U.S. at 669, 110 S.Ct. at 2688.

Attempts to address this problem had lingered since the 96th Congress (1979-80). H.R.Rep. No. 98-857(II) at 3, 1984

U.S.C.C.A.N. at 2687. Although the Senate passed legislation covering the area in 1982, it was thwarted in the House of Representatives on procedural grounds in September 1982. *Id.*

Hearings on the generic drug aspect of the legislation were held in the Committee of Energy and Commerce, Subcommittee on Health and the Environment in July 1983. After the subcommittee favorably reported the bill, Representative Henry Waxman of California conducted extensive negotiations with representatives of both generic and brand name pharmaceutical companies that generated a compromise that addressed the generic marketing and patent term aspects. This compromise was the basic language of the bill that became the Hatch-Waxman Act. *Id.* at 4, 1984 U.S.C.C.A.N. at 2688. Nearly a year later, the full committee marked-up the bill and adopted the compromise without further hearings. H.R.Rep. No. 98-857(I) at 16, 1984 U.S.C.C.A.N. 2649.

During the intervening time, in April 1984, the Court of Appeals for the Federal Circuit issued its decision in *Roche Products, Inc. v. Bolar Pharmaceuticals. Co., Inc.*, 733 F.2d 858 (Fed.Cir.1984). There, the court rejected the argument that using a drug for testing in order to prepare an application for approval from the FDA was a non-infringing use. *Id.* at 864-65. The Federal Circuit specifically held that it was up to Congress to address this concern. *Id.* This created a second distortion to the 17 year patent term[3] because competitors could not begin testing or seeking regulatory approval for their competing generic drugs until the patents of the pioneer drugs expired and thus could not compete in the marketplace for several years. *See Eli Lilly,* 496 U.S. at 670, 110 S.Ct. at 2688.

The Hatch-Waxman Act set out to correct these two distortions. Section 201 of the Hatch-Waxman Act provided

---

[3] The term of a patent has since been extended to 20 years.

for an extension of patents for certain drugs for up to five years to address the problem of the distorted patent term on the front end. *Id.* After the Federal Circuit issued its opinion in *Roche Products*, 733 F.2d 858, Section 202 was included in the bill, which added Section 271(e) to the Patent Act and was designed to address the distortion that effectively extended the patent term on the back end. *See Eli Lilly*, 496 U.S. at 671, 110 S.Ct. at 2689.

Hearings on Section 271(e) were held in the House Judiciary Committee, which was ordered to report on the bill within six weeks. H.R.Rep. No. 98-857(II) at 3, 1984 U.S.C.C.A.N. at 2687. The committee did not undertake a detailed examination of the type of claims that could be brought under Section 271(e)(2), but instead focused on whether Section 271(e)(1) amounted to an unconstitutional taking under the Fifth Amendment.[4] The Judiciary Committee reported the bill to the House on August 1, 1984.

In the intervening time, concerns about the bill were still being sounded by large pharmaceutical companies and the Patent and Trademark Office. The reservations threatened the bill's passage. *See* 130 Cong. Rec. 23,774 (1984) (statement of Sen. Baker). Senator Orrin Hatch of Utah, then chairman of the Senate Labor and Human Resources Committee, was Waxman's co-sponsor and had shepherded the bill through the Senate. In the waning days before the August recess, Hatch engaged in several marathon negotiating sessions in an effort to save the legislation. *Id.* Hatch's efforts were ultimately successful and led to several changes to the bill that kept intact its fundamental purpose of bringing generic drugs to the market quickly while maintaining broad bipartisan support. 130 Cong. Rec. 23,764 (1984). These changes included granting a five-year period of exclusivity in

---

[4] The House Judiciary Committee rejected that position, and the Supreme Court appears to have agreed in *Eli Lilly*, 496 U.S. at 678, 110 S.Ct. at 2693 n. 7.

marketing of new, unpatented drugs, codified at 21 U.S.C. § 355(c)(3)(D)(ii), in order to give incentives to drug makers to develop new medications; extending the period during which the FDA has to delay approval of an ANDA if a patentee brings suit under Section 217(e)(2) from 18 to 30 months, and clarifying the FDA's authority to disapprove ANDAs that are not identical to the pioneer drugs and in cases where the FDA is taking steps to remove the pioneer drug from the market. 130 Cong. Rec. 24,425. Having reached this compromise, the House passed the measure on September 6, 1984. The Senate followed six days later, and on September 24, 1984, President Reagan signed the Hatch-Waxman Act.

2. Jurisdictional Nature of Section 271(e)

Section 271(e)(2) provides in part that "[i]t shall be an act of infringement to submit an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . ." 35 U.S.C. § 271(e)(2)(A). Alcon admits[5] that its ANDA seeks approval for a drug for which Allergan has a valid patent claiming a method of use. Thus, Allergan argues that a "finding of no literal infringement . . . is potentially foreclosed in its entirety by the statute." (Allergan's Mem. of P. & A. in Opp'n to Mot. for Summ. J. at 10.) Allergan's literal reading of the statute is naturally problematic, as it would create a new and more expansive definition of infringement, and would appear to exclude traditional defenses such as invalidity and non-infringing use.[6] The Federal Circuit has

[5] Alcon's admissions are limited for use in the present motion only.

[6] At oral argument, Allergan insisted that it was not urging the Court to disregard the defense of invalidity. Nevertheless, that is the logical conclusion of Allergan's argument, as a literal reading does not encompass the invalidity defense. *Compare* 35 U.S.C. § 271(a) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent") *with* 35 U.S.C. § 271(e)(2).

also foreclosed this argument. In *Glaxo,* 110 F.3d at 1567, the Federal Circuit stated that "[t]he plain language of the statute does not alter a patentee's burden of proving infringement, nor does it mandate an infringement analysis limited to the scope of the [ANDA] approval sought."

The difficulty in a patent case brought under Section 271(e)(2) is that the allegedly infringing acts have not yet occurred. *Id.* The Court must engage in a hypothetical evaluation to determine what "is likely to be sold, or, preferably, what will be sold." *Id.* If the drug that will be sold upon approval of the ANDA is infringing, then the infringing maker will not be allowed to obtain approval of its ANDA. Ordinarily, such a hypothetical determination would run afoul of the "case or controversy" requirement of Article III. U.S. Const. art. III, § 2. Section 271(e)(2) therefore provides no new substantive law, but much like the Declaratory Judgment Act, 28 U.S.C. § 2201, merely provides a jurisdictional "hook" for a patent case. *Glaxo,* 110 F.3d at 1569 ("§ 271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction. . . .")

3. Scope of Claims that Can be Brought Under Section 271(e)(2)

Allergan argues that even if the submission of an ANDA does not constitute infringement per se, the Court must focus on whether it is likely that its patents will be infringed if Alcon is allowed to market its generic brimonidine, even though Alcon would not be the party using the drug in violation of Allergan's patent rights. Allergan's arguments, and the cases it relies on, tend to conflate the concepts of direct infringement under Section 271(e)(2) and inducing infringement under Section 271(b). The Court therefore sets out these two distinct arguments.[7]

---

[7] Allergan does not rely on a third possible ground, that Alcon would contributorily infringe the '415 and '741 Patents in violation of 35 U.S.C.

i. Direct Infringement

There is no question that, under a traditional infringement analysis, Alcon has not and will not infringe Allergan's patents. Alcon has made and seeks to sell the drug brimonidine, an old drug which has fallen into the public domain. As distinguished from the facts in *Glaxo*, where the plaintiff owned a patent that claimed both the compound per se and a method of creating it, *id.* at 1564, Allergan does not own a patent in the chemical brimonidine. Instead, the '415 and '741 Patents claim methods for using brimonidine. Under a traditional analysis, Allergan's patents will only be infringed if prescribing physicians use brimonidine as a neuroprotective agent, something Alcon cannot do.

Allergan's argument must therefore be based on an interpretation of the Hatch-Waxman Act as giving a pioneer drug maker/patentee a remedy against the generic drug maker for a wrong that will be committed in the future by someone else.

As set forth above, Section 271(e)(2) provides that "[i]t shall be an act of infringement to submit an [ANDA] for a drug . . . the use of which is claimed in a patent . . . ." 35 U.S.C. § 271(e)(2)(A). When looking at this language in isolation, an argument can be made that by enacting this statute, Congress was seeking to address precisely the situation now before the Court—a pioneer drug manufacturer such as Allergan invests substantial sums of money into research to find a new way to use an old drug. Although it cannot obtain a patent for the drug itself, as it has fallen into the public domain, it does obtain a patent on this new method of using

---

§ 271(c), as it concedes that brimonidine has non-infringing uses, specifically the reduction of IOP. In *Sony Corp. of America v. Universal City Studios, Inc. (The Betamax Case)*, 464 U.S. 417, 441-42 104 S.Ct. 774, 788 (1984), the Supreme Court examined the doctrine of contributory infringement in the context of patent law, and held that a party cannot be held liable as a contributory infringer if it manufactures a product that is adapted to non-infringing uses.

the drug, one which may well save significant suffering. But since the product itself was not patented, the generic drug manufacturer can swoop in, mass produce the drug, and leave physicians to their own devices as to how to prescribe the medicine.

Congress, one could argue, knew that it would be both impractical and bad business for the pioneer manufacturer to sue thousands of doctors across the country for patent infringement. Thus, it set up a no-fault system, disallowing the marketing of any generic drug if there is an unexpired patent claiming a method of using that drug, thereby stopping the infringing activity before it occurs. Unfortunately for Allergan, the structure of the Hatch-Waxman Act, its legislative history, and the specific problem that Section 271(e) was meant to address do not allow for such an interpretation.

In April 1984, the Federal Circuit, in *Roche Products*, 733 F.2d 858, held that there was no "experimental use" defense to patent infringement. As the district court in *Roche Products* found, cases prior to the Federal Circuit's decision had found that such experimental use did not give rise to a claim for infringement, or at least would not require a court to issue an injunction. *Roche Prods., Inc. v. Bolar Pharms. Co., Inc.*, 572 F.Supp. 255, 258 (E.D.N.Y.1983) (citing *Kaz Mfg. Co., Inc. v. Chesebrough-Pond's, Inc.*, 211 F.Supp. 815 (S.D.N.Y.1962), *aff'd*, 317 F.2d 679 (2d Cir.1963); *Maxon Premix Burner Co. v. Eclipse Fuel Eng'g Co.*, 471 F.2d 308 (7th Cir.1972)). Congress then hastily drafted Section 271(e) to reverse the decision and complete its work on the issue before the fall election. Thus, while most of the Hatch-Waxman was considered over a period of nearly six years and through several congressional hearings, Section 271(e) was drafted and reported out of the House Energy and Commerce Committee in just over six weeks. The only congressional hearings on Section 271(e) were focused on the constitutional takings issue and not on the practical impact of the statute.

The result, unsurprisingly, is a statute which even the Supreme Court has described as something less than an "elegant piece of statutory draftsmanship" requiring courts to engage in interpretation beyond the plain language. *Eli Lilly*, 496 U.S. at 679, 110 S.Ct. at 2693 (Scalia, J.).

In *Roche Products*, the patent at issue claimed the active ingredient in a prescription sleeping pill. 733 F.2d at 860. Unlike the present case, the patent claimed only the compound itself, not the use the drug. Thus, when drafting Section 271(e), Congress was primarily focused on exempting from infringement the use of a patented drug, not the use of a patented method of using that drug.

The structure of the Hatch-Waxman Act as a whole also does not allow for Allergan's claim here. This claim arose because when Alcon submitted its ANDA for generic brimonidine, it filed a Paragraph IV Certification asserting that the patents listed in the Orange Book were either invalid or not infringed. Pursuant to the requirements of a Paragraph IV Certification, it notified Allergan of the ANDA, which gave Allergan notice that it needed to bring this suit within 45 days. Under the Hatch-Waxman Act, however, it does not appear that Alcon was even required to file a Paragraph IV Certification.

A certification under paragraphs I-IV is required to be filed "with respect to each patent which claims the listed [i.e. pioneer] drug . . . or which claims a use for such listed drug for which the applicant is seeking approval . . . ." 21 U.S.C. § 355(j)(2)(A)(vii). In its report on the bill, the House Judiciary Committee set forth the process more clearly, stating that a certification under paragraphs I-IV was required only for "product patents . . . and all use patents which claim an indication for the drug which the applicant is seeking approval." H.R.Rep. No. 98-857(II) at 13, 1984 U.S.C.C.A.N. at 2697. The Judiciary Committee described these as "Controlling Use Patents." Under this definition, it is clear that the '415 and

'741 Patents are not Controlling Use Patents, as Alcon is not seeking approval for the indications claimed in those patents.

Furthermore, the House Energy and Commerce Committee explained that:

> if there are indications which are claimed by any use patent and for which the applicant is not seeking approval, then an ANDA must state that the applicant is not seeking approval for those indications which are claimed by such use patent. For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for indication No. 1, and not indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certification [under paragraphs I-IV] and a statement explaining that it is not seeking approval for indication No. 2.

H.R.Rep. No. 98-857(I) at 22, 1984 U.S.C.C.A.N. at 2656; *see also* 21 U.S.C. § 355(j)(2)(A)(viii). The example given by the House Energy and Commerce Committee is nearly identical to the situation now before the Court. Alcon is seeking approval to market brimonidine only for one indication, reducing IOP, and not for the second indication, as a neuroprotective agent,[8] because it is protected by a patent. Alcon therefore was not required under the law to file a Paragraph IV Certification.[9] It is the filing of a Paragraph IV Certification that puts into process the notice to the patentee

---

[8] In the present case, however, the second indication for using brimonidine as a neuroprotective agent is not even approved by the FDA.

[9] As a practical matter, however, filing the Paragraph IV Certification was the most prudent route given that the '415 and '741 Patents were listed in the Orange Book. It is worth noting that the regulations issued by the FDA suggest that the '415 and '741 Patents should not have even been listed in the Orange Book. The regulations, found at 21 C.F.R. § 314.53(b) provide that "[f]or patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application."

allowing it to bring suit under Section 271(e)(2). It does not withstand scrutiny to conjecture that Congress intended to design a system where a patentee could bring suit to prevent the approval of an ANDA in cases where it did not require the ANDA applicant to notify the patentee.

Infringement actions under Section 271(e)(2) must therefore be limited to the Controlling Use Patents. An ANDA which seeks approval only for indications that are not claimed in a patent does not violate Section 271(e)(2). Because there are no such Controlling Use Patents here, Alcon's ANDA does not directly infringe the '415 of '741 Patents.

ii. Inducing Infringement

Allergan alternatively argues that even if direct infringement cannot be shown, it has a right to prove that Alcon will, by sale of its generic brimonidine, induce infringement of the '415 and '741 Patents. Allergan claims that doctors who currently prescribe Alphagan® as a neuroprotective agent will prescribe Alcon's generic brimonidine not just to reduce IOP, but also for its neuroprotective use, thereby infringing Allergan's process patent.

Section 271(e), however, does not provide a predicate for Allergan to sue for inducing infringement. Although Allergan argues that Section 271(e) was enacted by Congress to provide a mechanism to adjudicate the issues of infringement before the generic drug comes to market, the purpose and effect of Section 271(e) is not so broad as Allergan would suggest.

Section 271(e) was designed to address the distortion to the end of the patent term that effectively extended a patentee's period of exclusivity. *Eli Lilly*, 496 U.S. at 671, 110 S.Ct. at 2689. Section 271(e)(1) exempts a party from liability for infringement if it makes, uses or sells a patented drug solely for the purpose of developing a generic drug to obtain regulatory approval. 35 U.S.C. § 271(e)(1). Section 271(e)(2),

however, creates what the Court has called a "somewhat artificial [ ] act of infringement," *Eli Lilly*, 496 U.S. at 676, 110 S.Ct. at 2691, when a party files an application to use that drug. 35 U.S.C. § 271(e)(2). The result is to bar a patent holder from suing for infringing use during the development and testing stage, but allow the patentee to sue under an expedited process once the infringer files for approval of the drug. Thus, what Congress taketh away in Section 271(e)(1), it giveth in Section 271(e)(2). The Court must therefore conclude that the type of claims that accrue upon the filing of an ANDA are limited to those claims that would have accrued earlier, when a generic drug maker used the patent to develop its generic drug.[10]

Viewed as such, a patent-holder cannot bring a claim under Section 271(e)(2) that the generic drug maker will, upon approval of the patent, induce others to infringe. As Allergan points out, the elements for inducing infringement are infringement by a third-party and "intent to encourage another's infringement." *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed.Cir.1990); *see also* 35 U.S.C. § 271(b). Had Section 271(e) not been enacted, Allergan in this case would have been able to sue Alcon for infringement for using its patent in the development of a generic drug. It could not, however, sue Alcon for inducing infringement because there was yet to be any third-party infringement and thus the question of inducing infringement would be entirely too speculative.[11]

---

[10] Allergan contends that this view of Section 271(e)(2) improperly looks backwards in time whereas *Glaxo* requires the Court to look to what will happen in the future. 110 F.3d at 1570. This is a misunderstanding of the Court's analysis. The Court is not looking backwards to determine whether there had been infringement, but merely looking backwards to see what causes of action Congress determined were justiciable under the Hatch-Waxman Act.

[11] Allergan argues that prior to the Hatch-Waxman Act, Alcon would have had to conduct clinical trials and distribute the drug to hundreds of

Allergan's argument that Section 271(e)(2) is the predicate act of infringement is circular. The only predicate act of infringement that Allergan alleges is Alcon's own filing of the ANDA.[12] Allergan argues that this allows the Court to examine what acts of infringement, including inducing infringement, Alcon will commit.

Allergan points to two unpublished district court decisions that it contends support its argument. *See Warner-Lambert,* 1999 WL 259946;[13] *see also In re Omeprazole Patent Litig.,* MDL Docket No. 1291 (citing *Warner-Lambert,* 1999 WL 259946, at *3). Both cases, like Allergan's argument here, conflate the issue of infringement under Section 271(e)(2) and the predicate act of infringement necessary to support a claim for inducing infringement. The district court in *Warner-Lambert* stated:

> Except for the district court's use of an *a priori* viewpoint, the court's "inquiry in a suit brought under § 271(e)(2) is the same as it is in any other infringement suit. . . ." Thus, in support of a suit brought under section 271(e)(2), a patent owner may rely on the theory that the commercial manufacture, use, or sale of a drug claimed

---

doctors to use, thereby inducing their infringement. The argument fails because that type of inducing infringement would not be speculative. The underlying infringing acts and the acts inducing the infringement would have already happened and the Court would not be forced to speculate on future actions by parties.

[12] It is undisputed that no prescribing physician has infringed Allergan's patents in either a traditional manner or by filing an ANDA.

[13] *Warner-Lambert* is not entirely favorable to Allergan, as the district court there, in a subsequent decision in that case, found that a claim for literal infringement under Section 271(e)(2) was foreclosed. *Warner-Lambert Co. v. Apotex Corp.,* No. 98 C 4293, 2001 WL 1104618, *3 n. 3 (N.D.Ill. Sept.14, 2001).

> in a patent or the use of which is claimed in a patent will actively induce the infringement of the owner's patent.

1999 WL 259946, at *3 (quoting *Glaxo,* 110 F.3d at 1569). While correct that the Court's inquiry under Section 271(e)(2) must be the same as in any other infringement suit, the remainder of this statement is erroneous for four reasons. First, the "exception" that the district court notes is a very important one indeed. As a practical matter, the *a priori* viewpoint of the Court requires it to speculate into what promotional efforts Alcon will undertake if its ANDA is approved and whether the physicians will then actually infringe the patent by prescribing its use as a neuroprotective agent. The speculation is not only practically difficult, but is constitutionally problematic. Because there has not been even a predicate act of infringement by the prescribing physicians, there is not a sufficiently immediate threat that there will be a violation of the patent laws so as to warrant judicial determination. *See Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273, 61 S.Ct. 510, 512, 85 L.Ed. 826 (1941). Thus, allowing a patentee to bring a claim for inducing infringement under Section 271(e)(2) runs afoul of the "case or controversy" requirement of Article III. U.S. Const. art. III, § 2.

Second, *Warner-Lambert* and *Omeprazole* both give a broad construction to Section 271(e)(2), yet it is well settled that "[s]tatutes purporting to confer federal subject matter jurisdiction must be narrowly construed, with ambiguities resolved against the assumption of jurisdiction." *Mars Inc. v. Kabushiki-Kaisha Nippon Conlux*, 24 F.3d 1368, 1373 (Fed.Cir.1994). Thus, even if a district court could, consistent with Article III, hear a case of inducing infringement when there has not yet been any third-party infringement, Congress must make a very explicit grant of jurisdiction. Section 271(e)(2) provides no such explicit grant.

Third, the court in *Warner-Lambert* did not examine Section 271(e) in light of the entirety of the Hatch-Waxman Act. The court there stated that "[n]owhere does the statute require that the proposed use of the generic drug be within the scope of the uses claimed in the patent in question for infringement to occur." 1999 WL 259946, at *3. This statement is plainly erroneous. Although it is not specifically stated in Section 271(e)(2), the Hatch-Waxman Act includes exactly this requirement, as the Court has set forth in part III.C.3.i, *supra.* In addition, Section 271(e)(4)(A) provides that the exclusive remedy for this case brought under Section 271(e)(2) is to delay FDA approval of the ANDA until the patents at issue expire. Even Allergan admits that the mere production of generic brimonidine does not infringe its patents, but that it must prove that Alcon has taken steps that would actively induce infringement. Yet the remedy for cases under Section 271(e)(2) would prevent the production of generic brimonidine and not address at all Alcon's active inducement. The result is akin to using a sledgehammer to squash an ant. If Congress had intended for Section 271(e)(2) to allow a claim for inducing infringement, it is fair to assume the remedy it prescribed would address the inducement.

Finally, neither the of the district courts in *Warner-Lambert* nor in *Omeprazole* examined the purpose of the Hatch-Waxman Act that created Section 271(e). As set forth above, the purpose of the Hatch-Waxman Act was to bring low cost generic drugs to market more quickly by exempting certain research uses from patent infringement liability, while still providing a jurisdictional "hook" for patentees to make their infringement claims before the drugs come to market. Accepting the interpretation of Section 271(e)(2) urged by Allergan, and adopted by the *Warner-Lambert* and *Omeprazole* courts, would not only allow a patentee to sue for those acts of infringement that, prior to the Hatch-Waxman Act, the patentee could have brought during the development of the drug, but would also allow the patentee to

sue for inducing an infringement that has not yet occurred. This interpretation turns the Congress's intent on its head. It would allow a pioneer drug manufacturer greater remedies than it had prior to the Hatch-Waxman Act and would allow them to block the manufacture of generic drugs by claiming inducing infringement whereas prior to the Hatch-Waxman Act, they could not.[14]

IV.

CONCLUSION

Accordingly, Alcon's motion for summary judgment on Allergan's complaint is GRANTED.

IT IS SO ORDERED.

---

[14] The result might be even more perverse in the present case, because if Allergan were to succeed, it would be able to effectively monopolize the market on all manufacture and use of brimonidine even though it admittedly can have no patent on the manufacture of brimonidine, and only has a patent on one of many uses for the drug.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

02-1449

ALLERGAN, INC. AND ALLERGAN SALES, INC.,
Plaintiffs-Appellants,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD.,
AND ALCON UNIVERSAL, LTD.,
Defendants-Appellees,

and

BAUSCH & LOMB INCORPORATED,
Defendant-Appellee.

Decided: May 22, 2003

ORDER

A petition for rehearing en banc having been filed by the APPELLANT,* and a response thereto having been invited by the court and filed by the APPELLEE, and the matter having first been referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service.

---

* Amicus curiae briefs were filed by:

1 - Generic Pharmaceutical Association.

2 - Washington Legal Foundation.

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on May 29, 2003.